

**Introduced by Senator Speier**

January 28, 1999

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An act to amend Sections 1368, 1368.01, 1368.03, and 1368.04 of, to amend, repeal, and add Section 1370.4 to, and to add and repeal Article 12 (commencing with Section 1399.80) to Chapter 2.2 of Division 2 of, the Health and Safety Code, relating to health insurance.

LEGISLATIVE COUNSEL'S DIGEST

SB 254, as introduced, Speier. Health insurance.

Under existing law, the Knox-Keene Health Care Service Plan Act of 1975, health care service plans are regulated by the Department of Corporations.

Existing law requires every health care service plan to establish and maintain a grievance system approved by the department under which enrollees and subscribers may submit their grievances to the plan. Under existing law, after participating for at least 60 days in, or completing, the plan's grievance process, an enrollee or subscriber may submit the grievance or complaint to the department for review.

This bill would require health care service plans to provide subscribers and enrollees with written responses to grievances, as specified, and would provide that a grievance may be submitted to the department by an enrollee or subscriber after participating in the plan's grievance process for 30 days. The bill would require the department to respond to each grievance in writing within 30 days.

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.

This bill would repeal this provision on January 1, 2001, and thereafter instead require every health care service plan to provide an enrollee with the opportunity to seek an independent medical review whenever health care services have been denied, significantly delayed, terminated, or otherwise limited by the plan or by one of its contracting providers.

This bill would establish, beginning January 1, 2001, the Independent Review System in the Department of Corporations, whereby enrollee grievances involving a disputed health care service or other adverse decision may be resolved by independent review organizations. The bill would set forth the duties and responsibilities of the department, health care service plans, and enrollees with respect to the system. It would provide that Medi-Cal and Medicare beneficiaries shall not be excluded from the system, to the extent that their participation is not preempted by federal law.

The bill would require the commissioner to contract with a private, nonprofit accrediting organization to accredit the independent review organizations, and would further require the adoption of related regulations.

This bill would require the commissioner, on or before July 1, 2000, to allocate grant funding for an independent health care ombudsprogram. It would require the department to contract with an independent expert entity to undertake an evaluation of the independent review system and the independent health care ombudsprogram. The bill would require the evaluator to provide its evaluation to the department on or before January 1, 2003, a copy of which shall be made available to the public.

The provisions of the bill relating to independent review would remain in effect only until January 1, 2004, and thereafter currently existing provisions limited to coverage decisions regarding experimental or investigational therapies would again become operative.



Under existing law, a willful violation of the provisions governing health care service plans is a crime. By changing the definition of the crime applicable to these 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. The Legislature finds and declares the  
2 following:  
3 (a) The California Managed Health Care  
4 Improvement Task Force has recommended that  
5 California enact an independent system of external  
6 review of health plan decisions. A similar  
7 recommendation was issued by the President's Advisory  
8 Commission on Consumer Protection and Quality in the  
9 Health Care Industry. Proponents of independent review  
10 maintain that this new program will enhance consumer  
11 confidence in health plan decisionmaking.  
12 (b) More than 15 states have enacted legislation  
13 establishing independent review of health care decisions,  
14 and in California, one health plan has voluntarily  
15 implemented a process for independent review of a  
16 broad range of unresolved patient grievances. In  
17 addition, Medicare has a system for independent review  
18 of unresolved patient grievances. A great diversity of  
19 policies and procedures has been applied to these various  
20 state and federal independent review systems.  
21 (c) Recent studies indicate only modest patient  
22 participation in state independent review programs,  
23 because many consumers are unaware of their right to  
24 access independent review. In addition, the studies  
25 indicate that many consumers in need of independent



1 review often are ill or disabled and do not have the ability  
2 to pursue an appeal, particularly if the rules are complex  
3 and they are not provided with advice and assistance to  
4 participate.

5 (d) The Legislature has convened efforts to reach a  
6 consensus on legislation to establish an independent  
7 review system within California. However, a consensus  
8 has not been achieved. In general, consumer,  
9 low-income, and senior groups are concerned about  
10 impediments to patient access to and participation in an  
11 independent review system. They are also concerned  
12 that expert reviewers may be biased in favor of health  
13 plans. Health plans, insurers, medical groups, and  
14 physicians are concerned about the potential for frivolous  
15 appeals burdening an independent review system. They  
16 are also concerned about the potential for excessive  
17 system costs being imposed.

18 (e) It would be in the state's best interest to proceed  
19 cautiously with a test of an independent review system  
20 that will sunset, with a report back to the Legislature a  
21 year prior to the sunset date to help determine whether  
22 to extend, modify, or terminate the program. The  
23 Legislature also finds that, in light of experience in other  
24 states that have implemented independent review  
25 systems, which shows only modest success in helping  
26 patients, the test in California should err on the side of  
27 promoting patient access, participation, and assistance.

28 SEC. 2. This act shall be known as the Patient's  
29 Independent Review Act of 1999.

30 SEC. 3. Section 1368 of the Health and Safety Code is  
31 amended to read:

32 1368. (a) Every plan shall do all of the following:

33 (1) Establish and maintain a grievance system  
34 approved by the department under which enrollees may  
35 submit their grievances to the plan. Each system shall  
36 provide reasonable procedures in accordance with  
37 department regulations that shall ensure adequate  
38 consideration of enrollee grievances and rectification  
39 when appropriate.



1 (2) Inform its subscribers and enrollees upon  
2 enrollment in the plan and annually thereafter of the  
3 procedure for processing and resolving grievances. The  
4 information shall include the location and telephone  
5 number where grievances may be submitted.

6 (3) Provide forms for ~~complaints~~ *grievances* to be  
7 given to subscribers and enrollees who wish to register  
8 written ~~complaints~~ *grievances*. The forms used by plans  
9 licensed pursuant to Section 1353 shall be approved by  
10 the commissioner in advance as to format.

11 (4) *Provide subscribers and enrollees with written*  
12 *responses to grievances, with a clear and concise*  
13 *explanation of the reasons for the plan's response. For*  
14 *grievances involving the denial, significant delay,*  
15 *termination, or the imposition of other limits on health*  
16 *care services, the plan response shall describe the criteria*  
17 *used and the clinical reasons for its decision, including all*  
18 *criteria and clinical reasons related to medical necessity*  
19 *or medical appropriateness.*

20 (5) Keep in its files all copies of ~~complaints~~ *grievances*,  
21 and the responses thereto, for a period of five years.

22 (b) (1) (A) After either completing the grievance  
23 process described in subdivision (a), or participating in  
24 the process for at least ~~60~~ 30 days, a subscriber or enrollee  
25 may submit the grievance ~~or—complaint~~ to the  
26 department for review. In any case determined by the  
27 department to be a case involving an imminent and  
28 serious threat to the health of the patient, including, but  
29 not limited to, *severe pain*, the potential loss of life, limb,  
30 or major bodily function, or in any other case where the  
31 department determines that an earlier review is  
32 warranted, a subscriber or enrollee shall not be required  
33 to complete the grievance process or participate in the  
34 process for at least ~~60—days~~ 30 days *before submitting a*  
35 *grievance to the department for review.*

36 (B) A grievance ~~or—complaint~~ may be submitted to the  
37 department for review and resolution prior to any  
38 arbitration.

39 (C) Notwithstanding subparagraphs (A) and (B), the  
40 department may refer any grievance ~~or—complaint~~ *issue*



1 *that does not pertain to compliance with this chapter to*  
2 the State Department of Health Services, the  
3 Department of Aging, the federal Health Care Financing  
4 Administration, or any other appropriate governmental  
5 entity for investigation and resolution.

6 (2) If the subscriber or enrollee is a minor, or is  
7 incompetent or incapacitated, the parent, guardian,  
8 conservator, relative, or other designee of the subscriber  
9 or enrollee, as appropriate, may submit the grievance ~~or~~  
10 ~~complaint~~ to the department as the agent of the  
11 subscriber or enrollee. further, a provider may join with,  
12 or otherwise assist, a subscriber or enrollee, or the agent,  
13 to submit the grievance ~~or complaint~~ to the department.  
14 In addition, following submission of the grievance ~~or~~  
15 ~~complaint~~ to the department, the subscriber or enrollee,  
16 or the agent, may authorize the provider to assist,  
17 including advocating on behalf of the subscriber or  
18 enrollee. For purposes of this section, a “relative”  
19 includes the parent, stepparent, spouse, adult son or  
20 daughter, grandparent, brother, sister, uncle, or aunt of  
21 the subscriber or enrollee.

22 (3) The department shall review the written  
23 documents submitted with the subscriber’s or the  
24 enrollee’s request for review, or submitted by the agent  
25 on behalf of the subscriber or enrollee. The department  
26 may ask for additional information, and may hold an  
27 informal meeting with the involved parties, including  
28 providers who have joined in submitting the grievance ~~or~~  
29 ~~complaint~~, or who are otherwise assisting or advocating  
30 on behalf of the subscriber or enrollee. *If, after reviewing*  
31 *the record, the department concludes that the grievance*  
32 *is eligible for review under the independent review*  
33 *system established pursuant to Article 12 (commencing*  
34 *with Section 1399.80), the department shall immediately*  
35 *notify the subscriber or enrollee, or agent, of that option*  
36 *and shall, if requested orally or in writing, assist the*  
37 *subscriber or enrollee to apply to participate in the*  
38 *independent medical review system.*

39 (4) *If, after reviewing the record of a grievance, the*  
40 *department concludes that the grievance was clearly*



1 eligible for review under the independent review system  
2 established pursuant to Article 12 (commencing with  
3 Section 1399.80), but this was not communicated to the  
4 enrollee in writing along with a notice of the enrollee's  
5 potential right to participate in the independent review  
6 system, as required by this chapter, the commissioner  
7 shall impose a penalty.

8 (5) The department shall send a written notice of the  
9 final disposition of the grievance ~~or complaint~~, and the  
10 reasons therefor, to the subscriber or enrollee, the agent,  
11 to any provider that has joined with or is otherwise  
12 assisting the subscriber or enrollee, and to the plan,  
13 within ~~60~~ 30 calendar days of receipt of the request for  
14 review unless the commissioner, in his or her discretion,  
15 determines that additional time is reasonably necessary  
16 to fully and fairly evaluate the relevant grievance ~~or~~  
17 ~~complaint~~. In any department response to an enrollee  
18 grievance not subject to the independent review system  
19 established pursuant to Article 12 (commencing with  
20 Section 1399.80), the department's written notice shall  
21 include, at a minimum, a brief description of the purpose  
22 of the department's review, the department's conclusion  
23 relating to the grievance along with a summary of the  
24 findings supporting the department's conclusion, the  
25 reasons why the department concluded that the plan is or  
26 is not in compliance with this chapter, and information  
27 about corrective and enforcement actions taken by the  
28 department.

29 (6) Distribution of the written notice shall not be  
30 deemed a waiver of any exemption or privilege under  
31 existing law, including, but not limited to, Section 6254.5  
32 of the Government Code, for any information in  
33 connection with and including the written notice, nor  
34 shall any person employed or in any way retained by the  
35 department be required to testify as to that information  
36 or notice. ~~On~~

37 (7) ~~On~~ or before January 1, ~~1997~~ 2000, the  
38 commissioner shall establish and maintain a system of  
39 aging of ~~complaints~~ grievances that are pending and  
40 unresolved for ~~60~~ 30 days or more, that shall include a



1 brief explanation of the reasons each ~~complaint~~ *grievance*  
2 is pending and unresolved for ~~60~~ 30 days or more.

3 (~~4~~)

4 (8) A subscriber or enrollee, or the agent acting on  
5 behalf of a subscriber or enrollee, may also request  
6 voluntary mediation with the plan prior to exercising the  
7 right to submit a grievance ~~or complaint~~ to the  
8 department. The use of mediation services shall not  
9 preclude the right to submit a grievance ~~or complaint~~ to  
10 the department upon completion of mediation. In order  
11 to initiate mediation, the subscriber or enrollee, or the  
12 agent acting on behalf of the subscriber or enrollee, and  
13 the plan shall voluntarily agree to mediation. Expenses  
14 for mediation shall be borne equally by both sides. The  
15 department shall have no administrative or enforcement  
16 responsibilities in connection with the voluntary  
17 mediation process authorized by this paragraph.

18 (c) The plan's grievance system shall include a system  
19 of aging of ~~complaints~~ *grievances* that are pending and  
20 unresolved for 30 days or more. On or before January 1,  
21 1997, the plan shall provide a quarterly report to the  
22 commissioner of ~~complaints~~ *grievances* pending and  
23 unresolved for 30 or more days with separate categories  
24 of ~~complaints~~ *grievances* for Medicare enrollees and  
25 Medi-Cal enrollees. The plan shall include with the report  
26 a brief explanation of the reasons each ~~complaint~~  
27 *grievance* is pending and unresolved for 30 days or more.  
28 The plan may include the following statement in the  
29 quarterly report that is made available to the public by  
30 the commissioner:

31

32 “Under Medicare and Medi-Cal law, Medicare  
33 enrollees and Medi-Cal enrollees each have separate  
34 avenues of appeal that are not available to other  
35 enrollees. Therefore, ~~complaints~~ *grievances* pending  
36 and unresolved may reflect enrollees pursuing their  
37 Medicare or Medi-Cal appeal rights.”

38

39 If requested by a plan, the commissioner shall include this  
40 statement in a written report made available to the public



1 and prepared by the commissioner that describes or  
2 compares ~~complaints~~ *grievances* that are pending and  
3 unresolved with the plan for 30 days or more.  
4 Additionally, the commissioner shall, if requested by a  
5 plan, append to that written report a brief explanation,  
6 provided in writing by the plan, of the reasons why  
7 ~~complaints~~ *grievances* described in that written report  
8 are pending and unresolved for 30 days or more. The  
9 commissioner shall not be required to include a statement  
10 or append a brief explanation to a written report that the  
11 commissioner is required to prepare under this chapter,  
12 including Sections 1380 and 1397.5.

13 (d) Subject to subparagraph (C) of paragraph (1) of  
14 subdivision (b), the *grievance*, ~~complaint~~, or resolution  
15 procedures authorized by this section shall be in addition  
16 to any other procedures that may be available to any  
17 person, and failure to pursue, exhaust, or engage in the  
18 procedures described in this section shall not preclude  
19 the use of any other remedy provided by law.

20 (e) Nothing in this section shall be construed to allow  
21 the submission to the department of any provider  
22 ~~complaint~~ or grievance under this section. However, as  
23 part of a provider's duty to advocate for medically  
24 appropriate health care for his or her patients pursuant  
25 to Sections 510 and 2056 of the Business and Professions  
26 Code, nothing in this subdivision shall be construed to  
27 prohibit a provider from contacting and informing the  
28 department about any concerns he or she has regarding  
29 compliance with or enforcement of this chapter.

30 SEC. 4. Section 1368.01 of the Health and Safety Code  
31 is amended to read:

32 1368.01. (a) The grievance system shall require the  
33 plan to resolve grievances within 30 days ~~whenever~~  
34 ~~possible~~ and shall require the plan to provide enrollees  
35 and subscribers with a written statement on the  
36 disposition or pending status of the grievance within ~~30~~  
37 *15* days of the plan's receipt of the grievance.

38 (b) The grievance system shall include a requirement  
39 for expedited plan review of grievances for cases  
40 involving an imminent and serious threat to the health of



1 the patient, including, but not limited to, *severe pain*,  
2 potential loss of life, limb, or major bodily function. When  
3 the plan has notice of a case requiring expedited review,  
4 the grievance system shall require the plan to  
5 immediately inform enrollees and subscribers in writing  
6 of their right to notify the department of the grievance.  
7 The grievance system shall also require the plan to  
8 provide enrollees, subscribers, and the department with  
9 a written statement on the disposition or pending status  
10 of the grievance no later than ~~five~~ *three* days from receipt  
11 of the grievance.

12 SEC. 5. Section 1368.03 of the Health and Safety Code  
13 is amended to read:

14 1368.03. (a) The department may require enrollees  
15 and subscribers to participate in a plan's grievance  
16 process for up to ~~60~~ *30* days before pursuing a ~~complaint~~  
17 *grievance* through the department. However, the  
18 department may not impose this waiting period ~~in~~ *for*  
19 *expedited review* cases covered by subdivision (b) of  
20 Section 1368.01 or in any other case where the  
21 department determines that an earlier review is  
22 warranted.

23 (b) Notwithstanding subdivision (a), the department  
24 may refer any grievance ~~or complaint~~ *issue that does not*  
25 *pertain to compliance with this chapter* to the State  
26 Department of Health Services, the Department of  
27 Aging, the federal Health Care Financing  
28 Administration, or any other appropriate governmental  
29 entity for investigation and resolution.

30 SEC. 6. Section 1368.04 of the Health and Safety Code  
31 is amended to read:

32 1368.04. (a) The commissioner shall, ~~as appropriate,~~  
33 investigate and take enforcement action against plans  
34 regarding ~~complaints by enrollees and subscribers~~  
35 *grievances reviewed and found by the department to*  
36 *involve plan noncompliance with the requirements of*  
37 *this chapter, including grievances that have been*  
38 *reviewed pursuant to the independent review system*  
39 *established pursuant to Article 12 (commencing with*  
40 *Section 1399.80). Where harm to an enrollee has occurred*



1 *as a result of plan noncompliance, the commissioner shall*  
2 *impose penalties.* The commissioner shall periodically  
3 evaluate ~~complaints~~ *grievances* to determine if any audit,  
4 investigative, or enforcement actions should be  
5 undertaken by the department.

6 (b) The commissioner may, after appropriate notice  
7 and opportunity for hearing, levy an administrative  
8 penalty, by order, in an amount not to exceed two  
9 hundred fifty thousand dollars (\$250,000) if the  
10 commissioner determines that a health care service plan  
11 has knowingly committed, or has performed with ~~such a~~  
12 frequency *so* as to indicate a general business practice,  
13 any of the following:

14 (1) Repeated failure to act promptly and reasonably to  
15 investigate and resolve grievances in accordance with  
16 Section 1368.01.

17 (2) Repeated failure to act promptly and reasonably to  
18 resolve grievances when the obligation of the plan to the  
19 enrollee or subscriber is reasonably clear.

20 (c) The administrative penalties available to the  
21 commissioner pursuant to this section are not exclusive,  
22 and may be sought and employed in any combination  
23 with civil, criminal, and other administrative remedies  
24 deemed warranted by the commissioner to enforce this  
25 chapter.

26 (d) The administrative penalties authorized pursuant  
27 to this section shall be paid to the State Corporations  
28 Fund.

29 SEC. 7. Section 1370.4 of the Health and Safety Code  
30 is amended to read:

31 1370.4. (a) Every health care service plan shall  
32 provide an external, independent review process to  
33 examine the plan's coverage decisions regarding  
34 experimental or investigational therapies for individual  
35 enrollees who meet all of the following criteria:

36 (1) The enrollee has a terminal condition that,  
37 according to the enrollee's physician's current diagnosis,  
38 has a high probability of causing death within two years  
39 from the date of the request for an independent review;  
40 and



1 (2) The enrollee's physician certifies that the enrollee  
2 has a condition, as defined in paragraph (1), for which  
3 standard therapies have not been effective in improving  
4 the condition of the enrollee, or for which standard  
5 therapies would not be medically appropriate for the  
6 enrollee, or for which there is no more beneficial standard  
7 therapy covered by the plan than the therapy proposed  
8 pursuant to paragraph (3); and

9 (3) Either (A) the enrollee's physician, who is under  
10 contract with or employed by the plan, has  
11 recommended a drug, device, procedure or other  
12 therapy that the physician certifies in writing is likely to  
13 be more beneficial to the enrollee than any available  
14 standard therapies, or (B) the enrollee, or the enrollee's  
15 physician who is a licensed, board-certified or  
16 board-eligible physician qualified to practice in the area  
17 of practice appropriate to treat the enrollee's condition,  
18 has requested a therapy that, based on two documents  
19 from the medical and scientific evidence, as defined in  
20 subdivision (d), is likely to be more beneficial for the  
21 enrollee than any available standard therapy. The  
22 physician certification pursuant to this subdivision shall  
23 include a statement of the evidence relied upon by the  
24 physician in certifying his or her recommendation.  
25 Nothing in this subdivision shall be construed to require  
26 the plan to pay for the services of a nonparticipating  
27 physician provided pursuant to this subdivision, that are  
28 not otherwise covered pursuant to the plan contract; and

29 (4) The enrollee has been denied coverage by the plan  
30 for a drug, device, procedure or other therapy  
31 recommended or requested pursuant to paragraph (3);  
32 and

33 (5) The specific drug, device, procedure or other  
34 therapy recommended pursuant to paragraph (3) would  
35 be a covered service, except for the plan's determination  
36 that the therapy is experimental or investigational; and

37 (6) This section shall not apply to any Medi-Cal  
38 beneficiary enrolled in a health care service plan under  
39 the plan's contract with the Medi-Cal program.



1 (b) The plan's external, independent review shall  
2 meet the following criteria:

3 (1) The plan shall offer all enrollees who meet the  
4 criteria in subdivision (a) the opportunity to have the  
5 requested therapy reviewed under the external,  
6 independent review process. The plan shall notify  
7 eligible enrollees in writing of the opportunity to request  
8 the external independent review within five business  
9 days of the decision to deny coverage.

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

28 (3) Neither the expert, nor the independent entity,  
29 nor any officer, director, or management employee of the  
30 independent entity shall have any material professional,  
31 familial, or financial affiliation, as defined in paragraph  
32 (4), with any of the following:

33 (A) The plan.

34 (B) Any officer, director, or management employee of  
35 the plan.

36 (C) The physician, the physician's medical group, or  
37 the independent practice association (IPA) proposing  
38 the therapy.

39 (D) The institution at which the therapy would be  
40 provided.



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

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

6 (A) “Material familial affiliation” shall mean any  
7 relationship as a spouse, child, parent, sibling, spouse’s  
8 parent, or child’s spouse.

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

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

29 (5) The enrollee shall not be required to pay for the  
30 external, independent review. The costs of the review  
31 shall be borne by the plan.

32 (6) The plan shall provide to the independent entity  
33 arranging for the panel of experts a copy of the following  
34 documents within five business days of the plan’s receipt  
35 of a request by an enrollee or enrollee’s physician for an  
36 external, independent review:

37 (A) The medical records relevant to the patient’s  
38 condition for which the proposed therapy has been  
39 recommended, provided the documents are within the  
40 plan’s possession. Any medical records provided to the



1 plan after the initial documents are provided to the  
2 independent entity shall be forwarded by the plan to the  
3 independent entity within five business days. The  
4 confidentiality of the medical records shall be maintained  
5 pursuant to Section 56.10 of the Civil Code.

6 (B) A copy of any relevant documents used by the plan  
7 in determining whether the proposed therapy should be  
8 covered, and any statement by the plan explaining the  
9 reasons for the plan's decision not to provide coverage for  
10 the proposed therapy. The plan shall provide, upon  
11 request, a copy of the documents required by this  
12 paragraph, except for the documents described in  
13 subparagraphs (A) and (C), to the enrollee and the  
14 enrollee's physician.

15 (C) Any information submitted by the enrollee or the  
16 enrollee's physician to the plan in support of the  
17 enrollee's request for coverage of the proposed drug,  
18 device, procedure, or other therapy.

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

30 (8) Each expert's analysis and recommendation shall  
31 be in written form and states the reasons the requested  
32 therapy is or is not likely to be more beneficial for the  
33 enrollee than any available standard therapy, and the  
34 reasons that the expert recommends that the therapy  
35 should or should not be provided by the plan, citing the  
36 enrollee's specific medical condition, the relevant  
37 documents provided pursuant to paragraph (6), and the  
38 relevant medical and scientific evidence, including, but  
39 not limited to, the medical and scientific evidence as



1 defined in subdivision (d), to support the expert's  
2 recommendation.

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

18 (10) If the majority of experts on the panel  
19 recommend providing the proposed therapy, pursuant to  
20 paragraph (8), the recommendation shall be binding on  
21 the plan. If the recommendations of the experts on the  
22 panel are evenly divided as to whether the therapy  
23 should be provided, then the panel's decision shall be  
24 deemed to be in favor of coverage. If less than a majority  
25 of the experts on the panel recommend providing the  
26 therapy, the plan is not required to provide the therapy.  
27 Coverage for the services required under this section  
28 shall be provided subject to the terms and conditions  
29 generally applicable to other benefits under the plan  
30 contract.

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

37 (c) The Commissioner of Corporations, in  
38 consultation with the Insurance Commissioner, shall, by  
39 January 1, 1998, contract with a private, nonprofit  
40 accrediting organization to accredit the independent



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

19 (d) For the purposes of paragraph (3) of subdivision  
20 (a), “medical and scientific evidence” means the  
21 following sources:

22 (1) Peer-reviewed scientific studies published in or  
23 accepted for publication by medical journals that meet  
24 nationally recognized requirements for scientific  
25 manuscripts and that submit most of their published  
26 articles for review by experts who are not part of the  
27 editorial staff.

28 (2) Peer-reviewed literature, biomedical compendia,  
29 and other medical literature that meet the criteria of the  
30 National Institute of Health’s National Library of  
31 Medicine for indexing in Index Medicus, Excerpta  
32 Medicus (EMBASE), Medline, and MEDLARS database  
33 Health Services Technology Assessment Research  
34 (HSTAR).

35 (3) Medical journals recognized by the Secretary of  
36 Health and Human Services, under Section 1861(t)(2) of  
37 the Social Security Act.

38 (4) The following standard reference compendia: The  
39 American Hospital Formulary Service-Drug  
40 Information, the American Medical Association Drug



1 Evaluation, the American Dental Association Accepted  
2 Dental Therapeutics, and the United States  
3 Pharmacopoeia-Drug Information.

4 (5) Findings, studies, or research conducted by or  
5 under the auspices of federal government agencies and  
6 nationally recognized federal research institutes  
7 including the Federal Agency for Health Care Policy and  
8 Research, National Institutes of Health, National Cancer  
9 Institute, National Academy of Sciences, Health Care  
10 Financing Administration, Congressional Office of  
11 Technology Assessment, and any national board  
12 recognized by the National Institutes of Health for the  
13 purpose of evaluating the medical value of health  
14 services.

15 (6) Peer-reviewed abstracts accepted for presentation  
16 at major medical association meetings.

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

20 (1) The independent entity must be an organization  
21 that has as its primary function to provide expert reviews  
22 and related services and receives a majority of its  
23 revenues from these services, except that an academic  
24 medical center may qualify as an independent entity for  
25 purposes of this act without having as its primary function  
26 providing expert reviews and related services and  
27 without receiving a majority of its revenues from these  
28 services. An independent entity may not be a subsidiary  
29 of, nor in any way owned or controlled by, a health plan,  
30 a trade association of health plans, or a professional  
31 association of health care providers.

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

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



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

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

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

13 (E) The percentage of revenue the independent  
14 entity receives from expert reviews.

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

18 (G) A description of the system the independent  
19 entity uses to identify and recruit expert reviewers, the  
20 number of expert reviewers credentialed and the types  
21 of cases the experts are credentialed to review.

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

27 (I) A description of the areas of expertise available  
28 from expert reviewers retained by the independent  
29 entity.

30 (J) A description of how the independent entity  
31 ensures compliance with the conflict-of-interest  
32 provisions of this section.

33 (3) The independent entity must demonstrate that it  
34 has a quality assurance mechanism in place that does the  
35 following:

36 (A) Ensures that the experts retained are  
37 appropriately credentialed and privileged.

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



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

6 (D) Ensures the confidentiality of medical records  
7 and the review materials, consistent with the  
8 requirements of this section.

9 (E) Ensures the independence of the experts retained  
10 to perform the reviews through conflict-of-interest  
11 policies and prohibitions and adequate screening for  
12 conflicts of interest, pursuant to paragraph (3) of  
13 subdivision (b).

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

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

27 (g) The independent review process established by  
28 this section shall be required on and after July 1, 1998.

29 (h) *This section shall remain in effect only until*  
30 *January 1, 2001, and as of that date is repealed, unless a*  
31 *later enacted statute, that becomes effective on or before*  
32 *January 1, 2001, deletes or extends that date.*

33 SEC. 8. Section 1370.4 is added to the Health and  
34 Safety Code, to read:

35 1370.4. (a) Every health care service plan shall  
36 provide an external, independent review process to  
37 examine the plan's coverage decisions regarding  
38 experimental or investigational therapies for individual  
39 enrollees who meet all of the following criteria:



1 (1) The enrollee has a terminal condition that,  
2 according to the enrollee's physician's current diagnosis,  
3 has a high probability of causing death within two years  
4 from the date of the request for an independent review;  
5 and

6 (2) The enrollee's physician certifies that the enrollee  
7 has a condition, as defined in paragraph (1), for which  
8 standard therapies have not been effective in improving  
9 the condition of the enrollee, or for which standard  
10 therapies would not be medically appropriate for the  
11 enrollee, or for which there is no more beneficial standard  
12 therapy covered by the plan than the therapy proposed  
13 pursuant to paragraph (3); and

14 (3) Either (A) the enrollee's physician, who is under  
15 contract with or employed by the plan, has  
16 recommended a drug, device, procedure or other  
17 therapy that the physician certifies in writing is likely to  
18 be more beneficial to the enrollee than any available  
19 standard therapies, or (B) the enrollee, or the enrollee's  
20 physician who is a licensed, board-certified or  
21 board-eligible physician qualified to practice in the area  
22 of practice appropriate to treat the enrollee's condition,  
23 has requested a therapy that, based on two documents  
24 from the medical and scientific evidence, as defined in  
25 subdivision (d), is likely to be more beneficial for the  
26 enrollee than any available standard therapy. The  
27 physician certification pursuant to this subdivision shall  
28 include a statement of the evidence relied upon by the  
29 physician in certifying his or her recommendation.  
30 Nothing in this subdivision shall be construed to require  
31 the plan to pay for the services of a nonparticipating  
32 physician provided pursuant to this subdivision, that are  
33 not otherwise covered pursuant to the plan contract; and

34 (4) The enrollee has been denied coverage by the plan  
35 for a drug, device, procedure or other therapy  
36 recommended or requested pursuant to paragraph (3);  
37 and

38 (5) The specific drug, device, procedure or other  
39 therapy recommended pursuant to paragraph (3) would



1 be a covered service, except for the plan's determination  
2 that the therapy is experimental or investigational; and

3 (6) This section shall not apply to any Medi-Cal  
4 beneficiary enrolled in a health care service plan under  
5 the plan's contract with the Medi-Cal program.

6 (b) The plan's external, independent review shall  
7 meet the following criteria:

8 (1) The plan shall offer all enrollees who meet the  
9 criteria in subdivision (a) the opportunity to have the  
10 requested therapy reviewed under the external,  
11 independent review process. The plan shall notify  
12 eligible enrollees in writing of the opportunity to request  
13 the external independent review within five business  
14 days of the decision to deny coverage.

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

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

38 (A) The plan.

39 (B) Any officer, director, or management employee of  
40 the plan.



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 enrollee whose treatment is under review.

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

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

14 (B) “Material professional affiliation” shall mean 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” shall not include affiliations  
22 which are limited to staff privileges at a health facility.

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

34 (5) The enrollee shall not be required to pay for the  
35 external, independent review. The costs of the review  
36 shall be borne by the plan.

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



1 of a request by an enrollee or enrollee's physician for an  
2 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 plan's possession. Any medical records provided to the  
7 plan after the initial documents are provided to the  
8 independent entity shall be forwarded by the plan to the  
9 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 plan  
13 in determining whether the proposed therapy should be  
14 covered, and any statement by the plan explaining the  
15 reasons for the plan's decision not to provide coverage for  
16 the proposed therapy. The plan shall provide, upon  
17 request, a copy of the documents required by this  
18 paragraph, except for the documents described in  
19 subparagraphs (A) and (C), to the enrollee and the  
20 enrollee's physician.

21 (C) Any information submitted by the enrollee or the  
22 enrollee's physician to the plan in support of the  
23 enrollee'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 enrollee's request for review. If the  
28 enrollee's physician determines that the proposed  
29 therapy would be significantly less effective if not  
30 promptly initiated, the analyses and recommendations of  
31 the experts on the panel shall be rendered within seven  
32 days of the request for expedited review. At the request  
33 of the expert, the deadline shall be extended by up to  
34 three days for a delay in providing the documents  
35 required by paragraph (6) of subdivision (b).

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



1 should or should not be provided by the plan, citing the  
2 enrollee'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 plan and  
9 the enrollee's physician with the experts' 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 plan and the enrollee'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 plan  
16 or the enrollee's physician, except pursuant to a properly  
17 made request for discovery. If the independent entity  
18 chooses to disclose the names of the experts on the panel  
19 to the plan, the independent entity must also disclose the  
20 names of the experts to the enrollee's physician. The  
21 enrollee's physician may provide these documents and  
22 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 plan. 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 plan is not required to provide the therapy.  
32 Coverage for the services required under this section  
33 shall be provided subject to the terms and conditions  
34 generally applicable to other benefits under the plan  
35 contract.

36 (11) The plan shall have written policies describing  
37 the external, independent review process. The plan shall  
38 disclose the availability of the external, independent  
39 review process and how enrollees may access the review



1 process in the plan's evidence of coverage and disclosure  
2 forms.

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

25 (d) For the purposes of paragraph (3) of subdivision  
26 (a), "medical and scientific evidence" means the  
27 following sources:

28 (1) Peer-reviewed scientific studies published in or  
29 accepted for publication by medical journals that meet  
30 nationally recognized requirements for scientific  
31 manuscripts and that submit most of their published  
32 articles for review by experts who are not part of the  
33 editorial staff.

34 (2) Peer-reviewed literature, biomedical compendia,  
35 and other medical literature that meet the criteria of the  
36 National Institute of Health's National Library of  
37 Medicine for indexing in Index Medicus, Excerpta  
38 Medicus (EMBASE), Medline, and MEDLARS database  
39 Health Services Technology Assessment Research  
40 (HSTAR).



1 (3) Medical journals recognized by the Secretary of  
2 Health and Human Services, under Section 1861(t)(2) of  
3 the Social Security Act.

4 (4) The following standard reference compendia: The  
5 American Hospital Formulary Service-Drug  
6 Information, the American Medical Association Drug  
7 Evaluation, the American Dental Association Accepted  
8 Dental Therapeutics, and the United States  
9 Pharmacopoeia-Drug Information.

10 (5) Findings, studies, or research conducted by or  
11 under the auspices of federal government agencies and  
12 nationally recognized federal research institutes  
13 including the Federal Agency for Health Care Policy and  
14 Research, National Institutes of Health, National Cancer  
15 Institute, National Academy of Sciences, Health Care  
16 Financing Administration, Congressional Office of  
17 Technology Assessment, and any national board  
18 recognized by the National Institutes of Health for the  
19 purpose of evaluating the medical value of health  
20 services.

21 (6) Peer-reviewed abstracts accepted for presentation  
22 at major medical association meetings.

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

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

38 (2) The independent entity must submit to the  
39 accrediting organization and to the Department of  
40 Corporations the following information upon initial



1 application for accreditation and annually thereafter  
2 upon any change to any of the following information:

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

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

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

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

18 (E) The percentage of revenue the independent  
19 entity receives from expert reviews.

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

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

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

32 (I) A description of the areas of expertise available  
33 from expert reviewers retained by the independent  
34 entity.

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

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



1 (A) Ensures that the experts retained are  
2 appropriately credentialed and privileged.

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

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

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

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

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

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

32 (g) The independent review process established by  
33 this section shall be required on and after January 1, 2004.

34 (h) This section shall become operative on January 1,  
35 2004.

36 SEC. 9. Article 12 (commencing with Section  
37 1399.80) is added to Chapter 2.2 of Division 2 of the Health  
38 and Safety Code, to read:

39



1 Article 12. Appeals Seeking Independent Reviews

2

3 1399.80. (a) Commencing January 1, 2001, there is  
4 established in the department the Independent Review  
5 System.

6 (b) For the purposes of this chapter, “disputed health  
7 care service” means any health care service that would  
8 otherwise be a covered benefit under a health care  
9 service plan contract that has been denied, significantly  
10 delayed, terminated, or otherwise limited by a decision of  
11 the plan, or by one of its contracting providers, based, in  
12 whole or in part, on a finding that the service is not  
13 medically necessary or appropriate for the enrollee’s  
14 medical condition.

15 (c) For the purposes of this chapter, “other adverse  
16 decision” means the denial, significant delay,  
17 termination, or the imposition of other limits on health  
18 care services by a plan, or by one of its contracting  
19 entities, for reasons other than those in subdivision (b).

20 (d) All enrollee grievances involving a disputed health  
21 care service or other adverse decision are eligible for  
22 review under the Independent Review System if the  
23 requirements of this chapter are met. If the department  
24 finds that an enrollee grievance does not meet the  
25 requirements of this chapter for review under the  
26 Independent Review System, the enrollee request for  
27 review shall be treated as a request for the department to  
28 review the grievance pursuant to subdivision (b) of  
29 Section 1368. All other enrollee grievances remain  
30 eligible for review by the department pursuant to  
31 subdivision (b) of Section 1368.

32 (e) No later than January 1, 2001, every health care  
33 service plan, except a specialized health care service plan,  
34 shall provide an enrollee with the opportunity to seek an  
35 independent review for unresolved grievances that  
36 involve a disputed health care service or other adverse  
37 decision. For purposes of this article, “enrollee” shall  
38 include a subscriber or designee as described in  
39 paragraph (2) of subdivision (b) of Section 1368. The  
40 enrollee’s provider may join with or otherwise assist the



1 enrollee to seek an independent medical review, and may  
2 advocate on behalf of the enrollee.

3 (f) Every health care service plan contract, except a  
4 specialized health care service plan contract, that is  
5 issued, amended, renewed, or delivered in this state on or  
6 after January 1, 2001, shall authorize enrollee  
7 participation in the Independent Review System.

8 (g) Medicare and Medi-Cal beneficiaries enrolled in a  
9 health care service plan shall not be excluded from  
10 participation in the Independent Review System. The  
11 department shall seek to integrate the quality of care and  
12 consumer protection provisions, including remedies, of  
13 the Independent Review System with related dispute  
14 resolution procedures of other health care agency  
15 programs, including the Medicare and Medi-Cal  
16 programs, in a way that minimizes the potential for  
17 duplication, conflict, and added costs. Nothing in this  
18 subdivision shall be construed to limit any rights  
19 conferred upon enrollees under this chapter. However,  
20 the application of this subdivision to a Medicare  
21 beneficiary shall not apply in the event, and to the extent,  
22 that application is judicially determined to be preempted  
23 by federal law.

24 (h) The independent review process authorized by  
25 this article is in addition to any other procedures or  
26 remedies that may be available. The enrollee's election to  
27 either pursue or not pursue, exhaust, or engage in the  
28 procedures described in this article does not preclude the  
29 use of any other remedy provided by law and shall not be  
30 relevant in any subsequent civil or administrative  
31 proceeding.

32 (i) No later than January 1, 2001, every health care  
33 service plan shall prominently display in every plan  
34 contract, on enrollee and subscriber evidence of  
35 coverage forms, on copies of plan procedures for  
36 resolving grievances, on the grievance forms required  
37 under Section 1368, and on all written notices to enrollees  
38 required under the grievance process of the plan,  
39 including any written communications to an enrollee that  
40 offer the enrollee the opportunity to participate in the



1 grievance process of the plan, and on all written responses  
2 to grievances, information concerning the right of an  
3 enrollee to request an independent review in cases where  
4 the enrollee believes that health care services have been  
5 improperly denied, significantly delayed, terminated, or  
6 otherwise limited by the plan, or by one of its contracting  
7 providers. Enrollees shall be notified of the availability of  
8 a standard application form to request an independent  
9 review.

10 (j) The department shall develop a standard  
11 application form for independent review that shall be  
12 used by each plan. An enrollee may apply for an  
13 independent review when all of the following conditions  
14 are met:

15 (1) The grievance involves a disputed health care  
16 service or other adverse decision and the enrollee first  
17 sought the health care service that is the subject of the  
18 grievance from an in-plan participating provider, except  
19 that the requirement to have first sought care from an  
20 in-plan provider shall not apply in cases involving  
21 emergency services or out-of-network urgent care.

22 (2) The health care service was denied, significantly  
23 delayed, terminated, or otherwise limited by the plan, or  
24 by one of its contracting providers, or in cases involving  
25 emergency services or urgent out-of-network care where  
26 the enrollee did not first seek care from a participating  
27 plan provider, the plan has denied reimbursement for the  
28 reasonable costs of securing such care.

29 (3) The enrollee has filed a grievance with the plan or  
30 its contracting provider pursuant to Section 1368, and the  
31 disputed decision is upheld or the grievance remains  
32 unresolved after 30 days. The enrollee shall not be  
33 required to participate in the plan's grievance process for  
34 more than 30 days. In the case of a grievance that requires  
35 expedited review pursuant to Section 1368.01, the  
36 enrollee shall not be required to participate in the plan's  
37 grievance process for more than three days.

38 (k) An enrollee may apply for an independent review  
39 within 60 days of any of the qualifying periods or events  
40 under subdivision (j), in a manner determined by the



1 commissioner. The commissioner may extend the  
2 application deadline beyond 60 days if the circumstances  
3 of a case warrant the extension. Each plan shall notify its  
4 enrollees of the commissioner's authority to extend the  
5 application deadline.

6 (l) As part of an appeal for an independent review, the  
7 enrollee shall provide all of the following:

8 (1) A brief description of the enrollee's medical  
9 condition for which health care services were denied,  
10 significantly delayed, terminated, or otherwise limited, or  
11 for which reimbursement for reasonable costs was  
12 denied.

13 (2) If the grievance involves a disputed health care  
14 service, an explanation of the reasons why the enrollee  
15 believes that the disputed health care service is or was  
16 medically necessary or appropriate for the enrollee's  
17 medical condition. If the grievance involves one or more  
18 other adverse decisions, an explanation of the reasons  
19 why the enrollee believes the plan's decision was  
20 incorrect.

21 The enrollee shall be encouraged to also provide other  
22 information supporting the enrollee's position as well as  
23 a copy of all information provided to the enrollee by the  
24 plan or any of its contracting providers, still in the  
25 possession of the enrollee, concerning a plan or provider  
26 decision regarding disputed health care services and  
27 services related to other adverse decisions, and a copy of  
28 any materials the enrollee submitted to the plan, still in  
29 the possession of the enrollee, in support of the grievance,  
30 as well as any additional material that the enrollee  
31 believes is relevant.

32 (3) A written consent to obtain any necessary medical  
33 records from the plan, any of its contracting providers,  
34 and any out-of-plan provider the enrollee may have  
35 consulted on the matter.

36 (m) (1) Upon receipt of an enrollee appeal for an  
37 independent review, the plan or its contracting providers  
38 shall provide the independent review organization a  
39 copy of all of the following documents within three



1 business days of the plan's receipt of the request by an  
2 enrollee for an independent review:

3 (A) A copy of all of the enrollee's medical records in  
4 the possession of the plan or its contracting providers  
5 relevant to each of the following:

6 (i) The enrollee's medical condition that is the subject  
7 of the independent review.

8 (ii) The health care services being provided by the  
9 plan and its contracting providers for the condition.

10 (iii) The health care services requested by the  
11 enrollee for the condition.

12 Any newly developed or discovered relevant medical  
13 records in the possession of the plan or its contracting  
14 providers after the initial documents are provided shall  
15 be forwarded immediately to the independent review  
16 organization. The plan shall concurrently provide a copy  
17 of medical records required by this subparagraph to the  
18 enrollee or the enrollee's provider unless the offer of  
19 medical records is declined or otherwise prohibited by  
20 law. The confidentiality of all medical record information  
21 shall be maintained pursuant to applicable state and  
22 federal laws.

23 (B) A copy of all information provided to the enrollee  
24 by the plan and any of its contracting providers  
25 concerning plan and provider decisions in response to the  
26 grievance, and a copy of any materials the enrollee or the  
27 enrollee's provider submitted to the plan and to the plan's  
28 contracting providers in support of the enrollee's  
29 grievance. This documentation shall include the written  
30 response to the enrollee's grievance, required by  
31 paragraph (4) of subdivision (a) of Section 1368, which  
32 requires, in part, a description of the criteria used and the  
33 clinical reasons for the decision, including all criteria and  
34 clinical reasons related to medical necessity or  
35 appropriateness. The confidentiality of any enrollee  
36 medical information shall be maintained pursuant to  
37 applicable state and federal laws.

38 (C) A copy of any other relevant documents or  
39 information used by the plan or its contracting providers  
40 in determining whether disputed health care services or



1 services subject to one or more other adverse decisions  
2 should have been provided, and any statements by the  
3 plan and its contracting providers explaining the reasons  
4 for the decision not to provide the services on the basis of  
5 medical necessity or appropriateness, or for any other  
6 reason. The plan shall concurrently provide a copy of  
7 documents required by this subparagraph, except for any  
8 information found by the commissioner to be legally  
9 privileged information, to the enrollee and the enrollee's  
10 provider. The department and the independent review  
11 organization shall maintain the confidentiality of any  
12 information found by the commissioner to be the  
13 proprietary information of the plan.

14 (2) The provisions of paragraph (1) requiring the  
15 referral of a grievance and related documents to an  
16 independent review organization shall not apply in cases  
17 where the plan files a written objection with the  
18 department and the enrollee, within three days of  
19 receiving a request for independent review, stating its  
20 belief that the requested appeal:

21 (A) Does not meet the eligibility requirements for  
22 independent review.

23 (B) Is frivolous and without merit.

24 (C) Is deficient due to both subparagraphs (A) and  
25 (B).

26 The written objection to the department shall be  
27 accompanied by a copy of the entire grievance record.  
28 The department shall establish an expedited process,  
29 which shall not exceed three days from receipt of an  
30 objection unless an extension is requested by the enrollee,  
31 for reviewing these cases and notifying the enrollee of its  
32 decision. If there is an imminent and serious threat to the  
33 health of the enrollee, as defined in subdivision (c) of  
34 Section 1399.83, the department shall accelerate its  
35 review of the objection. If the department disagrees with  
36 the plan's objection, the grievance shall be referred  
37 immediately to an independent review organization. If  
38 the department agrees with the plan, the grievance shall  
39 immediately be treated as a request for the department  
40 to review the grievance pursuant to subdivision (b) of



1 Section 1368. The department shall consider the entire  
2 grievance record, as well as any material submitted by the  
3 enrollee and the enrollee's providers, when making its  
4 decision regarding an objection.

5 1399.81. (a) Except in cases involving a plan  
6 objection submitted to the department, upon receipt of  
7 an enrollee's request for an independent review, the plan  
8 shall assign the request to an independent review  
9 organization as described in Section 1399.82 in  
10 accordance with any regulations or orders of the  
11 commissioner when the enrollee has complied with the  
12 requirements of subdivisions (j), (k), and (l) of Section  
13 1399.80.

14 (b) The independent review organization, which shall  
15 be selected by the department based on selection criteria  
16 developed by the department, shall conduct the review  
17 in accordance with Section 1399.83 and any regulations or  
18 orders of the commissioner adopted pursuant thereto.

19 1399.82. (a) By January 1, 2001, the commissioner  
20 shall make every effort to contract with one or more  
21 independent review organizations in the state to conduct  
22 reviews for purposes of this article. The independent  
23 review organizations shall be accredited pursuant to this  
24 article and shall be independent of any health care  
25 service plans doing business in this state. Prior to July 1,  
26 2000, the commissioner, after public notice, hearings, and  
27 comment, shall adopt regulations to ensure the  
28 independence of these organizations. The regulations  
29 shall include conflict-of-interest standards, consistent  
30 with the purposes of this article, that an organization shall  
31 be required to meet in order to qualify for participation  
32 in the Independent Review System.

33 (b) (1) The independent review organization, any  
34 experts it designates to conduct a review, or any officer,  
35 director, or employee of the independent entity shall  
36 have no material professional, familial, or financial  
37 affiliation, as determined by the commissioner, with any  
38 of the following:

39 (A) The plan.

40 (B) Any officer, director, or employee of the plan.



1 (C) A physician, the physician's medical group, or the  
2 independent practice association either denying or  
3 proposing the health care service in dispute.

4 (D) The institution at which either the proposed  
5 health care service, or the alternative service, if any,  
6 recommended by the plan, would be provided.

7 (E) The development or manufacture of the principal  
8 drug, device, procedure, or other therapy proposed by  
9 the enrollee whose treatment is under review, or the  
10 alternative therapy, if any, recommended by the plan.

11 (c) The commissioner shall, by July 1, 2000, contract  
12 with a private, nonprofit accrediting organization to  
13 accredit the independent review organizations described  
14 in subdivision (a). The accrediting organization may  
15 grant and revoke accreditation, and shall develop, apply,  
16 and enforce accreditation standards that ensure the  
17 independence of the independent review organization,  
18 the confidentiality of the medical records, and the  
19 qualifications and independence of the health care  
20 professionals and other experts providing the analyses  
21 and recommendations requested of them. The  
22 accrediting organization shall demonstrate the ability to  
23 objectively evaluate the performance of independent  
24 review organizations and shall demonstrate that it has no  
25 conflict of interest, including any material professional,  
26 familial, or financial affiliation, as provided in subdivision  
27 (b), with any independent review organization or plan,  
28 in accrediting those organizations for the purpose of  
29 reviewing disputed health care decisions and other  
30 adverse decisions made by health care service plans.

31 (d) Prior to July 1, 2000, the commissioner, after public  
32 notice, hearings, and comment, shall adopt regulations  
33 related to the accreditation of independent review  
34 organizations. In developing the regulations required by  
35 this subdivision, the department shall consider adopting  
36 the following, but may accept, reject, or modify the  
37 following based on information received as a result of the  
38 rulemaking process. If the department rejects or modifies  
39 any of the following, it shall discuss its reasons for doing  
40 so in the final rulemaking document. In order to receive



1 accreditation for the purposes of this section, an  
2 independent review organization shall meet all of the  
3 following requirements:

4 (1) An independent review organization shall not be  
5 an affiliate or a subsidiary of, nor in any way be owned or  
6 controlled by, a health plan, or a trade association of  
7 health plans. A board member, director, officer, or  
8 employee of the independent review organization shall  
9 not serve as a board member, director, or employee of a  
10 health care service plan. A board member, director, or  
11 officer of a health plan or a trade association of health  
12 plans shall not serve as a board member, director, officer,  
13 or employee of an independent review organization.

14 (2) The independent review organization shall submit  
15 to the accrediting organization and to the department  
16 the following information upon initial application for  
17 accreditation and, except as otherwise provided, annually  
18 thereafter upon any change to any of the following  
19 information:

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

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

25 (C) The names of all corporations and organizations  
26 that the independent review organization controls or is  
27 affiliated with, and the nature and extent of any  
28 ownership or control, including the affiliated  
29 organization's type of business.

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

38 (E) (i) The percentage of revenue the independent  
39 review organization receives from expert reviews,



1 including, but not limited to, external medical reviews,  
2 quality assurance reviews, and utilization reviews.

3 (ii) The names of any health care service plan or  
4 provider group for which the independent review  
5 organization provides review services, including, but not  
6 limited to, utilization review, quality assurance review,  
7 and external medical review. Any change in this  
8 information shall be reported to the department within  
9 five business days of the change.

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

13 (G) A description of the system the independent  
14 review organization uses to identify and recruit medical  
15 professionals and other experts to review disputed health  
16 care decisions and other adverse decisions made by  
17 health care service plans, the number of medical  
18 professionals credentialed, and the types of cases and  
19 areas of expertise which the medical professionals are  
20 credentialed to review, and the number of other experts,  
21 the types of cases and areas of expertise which those other  
22 experts are licensed or credentialed to review.

23 (H) A description of how the independent review  
24 organization ensures compliance with the  
25 conflict-of-interest provisions of this section.

26 (3) The independent review organization shall  
27 demonstrate that it has a quality assurance mechanism in  
28 place that does the following:

29 (A) Ensures that the medical professionals retained  
30 are appropriately credentialed and privileged and that  
31 the other experts retained are appropriately qualified,  
32 licensed, and credentialed.

33 (B) Ensures that the reviews provided by the medical  
34 professionals and other experts are timely, clear, and  
35 credible, and that reviews are monitored for quality on an  
36 ongoing basis.

37 (C) Ensures that the method of selecting medical  
38 professionals and other experts for individual cases  
39 achieves a fair and impartial panel of medical  
40 professionals and other experts who are qualified to



1 render recommendations regarding disputed health care  
2 decisions and other adverse decisions made by health  
3 care service plans.

4 (D) Ensures the confidentiality of medical records  
5 and the review materials, consistent with the  
6 requirements of this section and applicable state and  
7 federal law.

8 (E) Ensures the independence of the medical  
9 professionals and other experts retained to perform the  
10 reviews through conflict-of-interest policies and  
11 prohibitions, and ensures adequate screening for conflicts  
12 of interest, pursuant to paragraph (5).

13 (4) Medical professionals selected by independent  
14 review organizations to review medical treatment  
15 decisions shall be physicians or other appropriate  
16 providers who meet the following minimum  
17 requirements:

18 (A) The medical professional shall be a clinician  
19 knowledgeable in the treatment of the enrollee's medical  
20 condition, knowledgeable about the proposed treatment,  
21 and familiar with guidelines, protocols, and the criteria  
22 set forth in subdivision (b) of Section 1399.83 in the area  
23 of treatment under review.

24 (B) The medical professional shall hold a  
25 nonrestricted license in the State of California, and for  
26 physicians, a current certification by a recognized  
27 American medical specialty board in the area or areas  
28 appropriate to the condition or treatment under review.  
29 For good cause shown, such as the unavailability of  
30 licensed qualified medical professionals in California or  
31 the availability of uniquely qualified clinics outside of  
32 California, the independent review organization may  
33 utilize a medical professional who holds a nonrestricted  
34 license in any state of the United States, provided that the  
35 out-of-state medical professional is knowledgeable about  
36 the treatment standards required in California and  
37 applies those standards.

38 (C) The medical professional and other experts shall  
39 have no history of disciplinary action or sanctions,  
40 including, but not limited to, loss of staff privileges or



1 participation restrictions, taken or pending by any  
2 hospital, government, or regulatory body.

3 (5) Neither the expert reviewer, nor the independent  
4 review organization, shall have any material professional,  
5 material familial, or material financial affiliation with any  
6 of the following:

7 (A) The plan or a provider group of the plan, except  
8 that an academic medical center under contract to the  
9 plan to provide services to enrollees may qualify as an  
10 independent review organization provided it will not  
11 provide the service and provided the center is not the  
12 developer or manufacturer of the proposed treatment.

13 (B) Any officer, director, or management employee of  
14 the plan.

15 (C) The physician, the physician's medical group, or  
16 the independent practice association (IPA) proposing  
17 the treatment.

18 (D) The institution at which the treatment would be  
19 provided.

20 (E) The development or manufacture of the  
21 treatment proposed for the enrollee whose condition is  
22 under review.

23 (F) The enrollee or the enrollee's immediate family.

24 (6) For purposes of this section, the following terms  
25 shall have the following meanings:

26 (A) "Material familial affiliation" means any  
27 relationship as a spouse, child, parent, sibling, spouse's  
28 parent, or child's spouse.

29 (B) "Material professional affiliation" means any  
30 physician-patient relationship, any partnership or  
31 employment relationship, a shareholder or similar  
32 ownership interest in a professional corporation, or any  
33 independent contractor arrangement that constitutes a  
34 material financial affiliation with any expert or any officer  
35 or director of the independent review organization.

36 "Material professional affiliation" does not include  
37 affiliations that are limited to staff privileges at a health  
38 facility.

39 (C) "Material financial affiliation" means any financial  
40 interest of more than 5 percent of total annual revenue



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

11 (e) The accrediting organization shall provide, upon  
12 the request of any interested person, a copy of all  
13 nonproprietary information, as determined by the  
14 commissioner, filed with it by an independent review  
15 organization seeking accreditation under this article. The  
16 accrediting organization may charge a nominal fee to the  
17 interested person for photocopying the requested  
18 information.

19 (f) The independent review process established by  
20 this article shall not commence until one or more  
21 independent review organizations have been accredited  
22 and have executed a contract with the department  
23 pursuant to this section.

24 1399.83. (a) Upon receipt of information and  
25 documents related to a case pursuant to subdivision (c)  
26 of Section 1399.81, the expert reviewer or reviewers  
27 selected to conduct the review by the independent  
28 review organization shall promptly review all pertinent  
29 medical records of the enrollee, provider reports, as well  
30 as any other information submitted to the organization as  
31 authorized by the department or requested from any of  
32 the parties to the dispute by the reviewers. If reviewers  
33 request information from any of the parties, a copy of the  
34 request and the response shall be provided to all of the  
35 parties.

36 (b) (1) Following its review of a grievance involving  
37 a disputed health care service, the medical expert  
38 reviewer or reviewers shall determine and state whether  
39 the disputed health care service is or was medically  
40 necessary or appropriate based on:



1 (A) Generally accepted practice guidelines  
2 developed by federal agencies, nationally recognized  
3 federal research institutes, or national professional  
4 medical specialty societies.

5 (B) Relevant medical or scientific evidence, if any  
6 exists, regarding the clinical value of the disputed health  
7 care service.

8 (C) Generally accepted standards of medical practice.

9 (D) Treatments that are likely to provide a benefit to  
10 a patient for conditions for which other treatments are  
11 not clinically efficacious.

12 (2) Medically necessary or appropriate health care  
13 services shall include those related to treatment or  
14 therapy to maximize functional capacity. This subdivision  
15 is to be construed in the best interests of the enrollee.

16 (c) Following its review of a grievance involving one  
17 or more other adverse decisions, the expert reviewer or  
18 reviewers shall determine and state whether the decision  
19 to deny, significantly delay, terminate, or otherwise  
20 impose limits on health care services was reasonable  
21 taking into consideration, among other relevant  
22 information, all of the provisions of the enrollee's health  
23 care service plan contract.

24 (d) The independent review organization shall  
25 require its expert reviewers to complete a review and  
26 make a determination in writing, and in layperson's terms  
27 to the maximum extent practicable, within 30 days of the  
28 receipt by the independent review organization of the  
29 application for review and supporting documentation, or  
30 within less time as prescribed by the commissioner. If a  
31 requested health care service that is the subject of the  
32 grievance has not been provided and the enrollee's  
33 provider or the department certifies in writing that an  
34 imminent and serious threat to the health of the enrollee  
35 may exist, including, but not limited to, serious pain, the  
36 potential loss of life, limb, or major bodily function, or the  
37 immediate and serious deterioration of the health of the  
38 enrollee, the analyses and determinations of the  
39 reviewers shall be expedited and rendered within three  
40 days of the certification notice. Subject to the approval of



1 the department, the deadlines for analyses and  
2 determinations involving both regular and expedited  
3 reviews may be extended by up to three days following  
4 reviewer receipt of delayed documentation required by  
5 this chapter.

6 (e) Each analysis shall cite the enrollee's medical  
7 condition and the relevant documents in the record to  
8 support the determination.

9 (f) In cases involving disputed health care services,  
10 each analysis shall cite relevant findings associated with  
11 the provisions of subdivision (b). If more than one  
12 medical expert reviews the case, the recommendation of  
13 the majority shall prevail. If the medical experts  
14 reviewing the case are evenly split as to whether the  
15 disputed health care service is or was medically necessary  
16 or appropriate, the decision shall be in favor of the  
17 enrollee.

18 (g) In cases related to a grievance involving one or  
19 more other adverse decisions, if more than one expert  
20 reviews the case, the recommendation of the majority  
21 shall prevail. If the experts reviewing the case are evenly  
22 split as to whether it was reasonable to deny, significantly  
23 delay, terminate, or otherwise impose limits on health  
24 care services, the decision shall be in favor of the enrollee.

25 (h) The independent review organization shall  
26 provide the commissioner with the analyses and  
27 determinations of the experts reviewing the case, a  
28 description of the qualifications of the experts, and the  
29 names of the reviewers. If more than one expert reviewed  
30 the case and the result was differing determinations, the  
31 independent review organization shall provide the  
32 commissioner with each of the separate reviewer  
33 analyses and determinations.

34 (i) The commissioner, except in cases subject to  
35 expedited reconsideration under subdivision (j), shall  
36 immediately adopt the determination of the  
37 independent review organization, and shall promptly  
38 issue a written decision to the parties, which decision shall  
39 be binding on the plan as an order.



1 (j) The commissioner may request the independent  
2 review organization, on an expedited basis, to reconsider  
3 any determination involving one or more other adverse  
4 decisions when the commissioner finds that the  
5 determination is clearly contrary to the legal  
6 requirements of this chapter or other laws. If after  
7 reconsideration, the independent review organization  
8 renders a determination that the commissioner finds  
9 remains clearly contrary to the legal requirements of this  
10 chapter or other law, the commissioner shall forward the  
11 determination to the parties, along with the  
12 commissioner's finding, and the disputed portion of the  
13 determination involving one or more other adverse  
14 decisions shall not be binding. In these cases, the  
15 department shall immediately treat that portion of the  
16 grievance related to the disputed determination  
17 pursuant to subdivision (b) of Section 1368.

18 (k) Nothing about the independent review process  
19 established by this article, including, but not limited to,  
20 the analysis, recommendations, and conclusions of the  
21 review panel, shall be admissible in any subsequent  
22 proceeding.

23 (l) After removing the names of the parties, including,  
24 but not limited to, the enrollee, all medical providers, the  
25 plan, and any of its employees or contractors,  
26 commissioner orders adopting a determination of an  
27 independent review organization shall be made available  
28 by the department to the public upon request, at the  
29 department's cost.

30 1399.84. (a) Upon receiving the order adopted by the  
31 commissioner pursuant to subdivision (i) or (j) of Section  
32 1399.83, the plan shall immediately contact the enrollee  
33 and offer to promptly implement the order.

34 (b) In any case where an enrollee secured urgent care  
35 or emergency services outside of the plan provider  
36 network, and these services are later found by the  
37 independent review organization to have been a covered  
38 benefit under the terms and conditions of the health care  
39 service plan contract and were medically necessary or  
40 appropriate, the commissioner shall require the plan to



1 promptly reimburse the enrollee for any reasonable costs  
2 associated with those services when the commissioner  
3 finds that the enrollee's decision to secure the services  
4 outside of the plan provider network prior to seeking an  
5 independent review was reasonable under the  
6 circumstances.

7 (c) In addition to requiring plan compliance  
8 regarding subdivisions (a) and (b), the commissioner  
9 shall review individual cases submitted for independent  
10 review to determine whether any enforcement actions,  
11 including penalties, may be appropriate. In particular,  
12 where harm to an enrollee has already occurred because  
13 of the decision of a plan, or one of its contracting  
14 providers, to deny, significantly delay, terminate, or  
15 otherwise limit covered health care services that an  
16 independent review determines to be medically  
17 necessary or appropriate, the commissioner shall impose  
18 penalties.

19 (d) Pursuant to Section 1368.04, the commissioner  
20 shall periodically evaluate independent review cases to  
21 determine if any audit, investigative, or enforcement  
22 actions should be undertaken by the department,  
23 particularly if a plan repeatedly fails to act promptly and  
24 reasonably to resolve grievances associated with a denial,  
25 significant delay, termination, or the imposition of other  
26 limits on medically necessary or appropriate health care  
27 services when the obligation of the plan to provide those  
28 health care services to enrollees or subscribers is  
29 reasonably clear.

30 1399.85. (a) After considering the results of a  
31 competitive bidding process and any other relevant  
32 information on program costs, the commissioner shall  
33 establish a reasonable, per-case reimbursement schedule  
34 to pay the costs of independent review organization  
35 reviews, which may vary depending on the type of  
36 medical condition under review and on other relevant  
37 factors.

38 (b) As a condition for receiving payments for reviews,  
39 independent review organizations shall agree to provide



1 reasonable data required for an evaluation of the  
2 independent review system.

3 1399.86. (a) On or before July 1, 2000, the  
4 commissioner shall allocate grant funding for an  
5 independent health care ombudsprogram. At a  
6 minimum, the commissioner shall approve project grants  
7 for at least one new or existing independent assistance  
8 project in southern, central, and northern California if  
9 qualified applicants apply from each of those three  
10 regions. The number of projects approved shall  
11 eventually be sufficient to provide independent  
12 assistance to all California enrollees. However, in order to  
13 facilitate the start-up and effective implementation of  
14 this section, the commissioner may take until July 1, 2002,  
15 if necessary, to fund a sufficient number of projects to  
16 serve all California enrollees.

17 (b) Project activities shall include, but are not limited  
18 to, providing counseling, advising, assisting, and  
19 advocating for enrollees at every stage of:

20 (A) The health plan grievance process.

21 (B) The department's grievance review process  
22 under subdivision (b) of Section 1368.

23 (C) Applying for and participating in the  
24 Independent Review System.

25 (c) All of the projects shall, as necessary and  
26 appropriate, directly assist enrollees in their dealings with  
27 plans, provider groups, providers, and government  
28 agencies, including advocating on behalf of enrollees in  
29 any informal or formal proceeding.

30 (d) The commissioner shall use a competitive bidding  
31 process to select projects. The projects shall be selected  
32 based on, but not limited to, all of the following selection  
33 criteria:

34 (1) The applicant's experience providing enrollees  
35 with education, counseling, and advocacy services.

36 (2) The number of enrollees covered by health plans  
37 served by the project and the size of the geographic  
38 region to be served by the project.

39 (3) Evidence of an understanding of the range and  
40 complexity of health care concerns likely to be raised by



1 enrollees, including vulnerable populations served by  
2 various health plans.

3 (4) The number and quality of staff with formal  
4 training and experience in health care, counseling, and  
5 consumer advocacy.

6 (5) The ability to complement, and not duplicate,  
7 existing consumer services provided by health plans,  
8 other independent assistance programs, and regulatory  
9 assistance programs, which shall include a commitment  
10 to refer enrollees, as appropriate, to the Health Insurance  
11 Counseling and Advocacy Program (HICAP) in cases  
12 eligible for HICAP assistance.

13 (6) The commitment to collect and analyze data on  
14 enrollee experiences in health plan grievance systems, in  
15 the department's grievance review process, and in the  
16 Independent Review System.

17 (7) The ability and commitment to provide significant  
18 matching contributions to support the program in the  
19 form of private or public financial support or in-kind  
20 contributions, or a combination of the two.

21 (8) The commitment to provide project services to  
22 enrollees free of charge.

23 (9) The degree of consumer representation on the  
24 applicant's governing advisory board, if such a board  
25 exists.

26 (e) The evaluation of bids submitted pursuant to  
27 subdivision (d) shall be conducted by the commissioner  
28 in consultation with a panel of at least three individuals  
29 screened and appointed by the commissioner who have  
30 no conflicts of interest including, but not limited to, a  
31 financial interest in the outcome of the bidding process,  
32 or employment or contractual arrangements with plans,  
33 their contracting medical groups or contracting  
34 providers, and who have significant experience with, and  
35 knowledge about, managed health care issues, health  
36 care dispute resolution mechanisms, and consumer  
37 advocacy.

38 (f) Funding for the projects shall commence no earlier  
39 than July 1, 2000, and may continue for a period extending  
40 no later than December 31, 2003.



1 (g) As a condition for receiving funding, each of the  
2 projects shall agree to provide reasonable data required  
3 for an evaluation of the independent health care  
4 ombudsprogram.

5 1399.87. (a) The costs of the independent review  
6 system and independent health care ombudsprogram  
7 shall be borne by health care service plans pursuant to an  
8 assessment fee system established by the commissioner.  
9 Every health care service plan shall pay annually to the  
10 department, on the date or dates set by the department,  
11 its prorated share of fees, as determined by the  
12 commissioner, to pay for the estimated annual costs  
13 associated with carrying out, overseeing, and evaluating  
14 the independent review system and independent health  
15 care ombudsprogram. In determining the amount to be  
16 assessed, the commissioner shall consider all existing  
17 assessments and appropriations available for the support  
18 of this chapter including any offsetting funds that can be  
19 made available as a result of enrollee grievances being  
20 diverted from the department and reviewed instead by  
21 independent review organizations with enrollees assisted  
22 by the independent health care ombudsprogram instead  
23 of by department staff. The commissioner may adjust fees  
24 upward or downward, on a schedule set by the  
25 department, to address shortages or overpayments.

26 (b) The portion of the assessment fee imposed by  
27 subdivision (a) to pay for the independent health care  
28 ombudsprogram shall not apply to any health care service  
29 plan that is funding and has in place by July 1, 2000, or  
30 thereafter, an independent, external health care  
31 ombudsprogram certified by the commissioner as  
32 substantially complying with the selection criteria for  
33 eligibility utilized under this chapter, and provided that  
34 the health plan ombudsprogram agrees to collect and  
35 provide reasonable data to the department and its  
36 evaluator in accordance with subdivisions (a) and (b) of  
37 Section 1399.88. The commissioner's certification review  
38 shall be done in consultation with the panel established  
39 pursuant to subdivision (e) of Section 1399.86.



1 (c) These funds shall be used for all costs reasonably  
2 incurred in the administration of this article, including,  
3 but not limited to, startup costs, overhead, department  
4 administration, contracting with an accrediting  
5 organization, contracts with independent review  
6 organizations, payments to expert reviewers, grants for  
7 ombudsprogram projects and program evaluation.

8 1399.88. (a) The department shall contract with an  
9 independent expert entity to undertake an evaluation of  
10 the independent review system and the independent  
11 health care ombudsprogram.

12 (b) The independent evaluation shall include, but not  
13 be limited to, an assessment of the effectiveness and value  
14 of the independent review system and the  
15 ombudsprogram. The evaluation shall include a  
16 description of assessments imposed on plans to  
17 implement these programs, changes in department  
18 staffing attributable to these new programs, any increase,  
19 reduction, or redirection of existing department staff as  
20 a result of these new programs, and any changes in  
21 department workload attributed to enrollee use of the  
22 ombudsprogram and the referral of grievances to the  
23 independent review system.

24 (c) The evaluation shall assess the long-term efficacy  
25 of these programs as a means of providing timely and  
26 effective resolution of enrollee grievances with plans, and  
27 for improving access to and the quality of health care  
28 services, and as a catalyst for systemic improvements in  
29 the delivery of health care services. In addition to  
30 reviewing data generated by these new California  
31 programs, the evaluator shall survey and report on similar  
32 programs underway in other states.

33 (d) The evaluator shall provide its evaluation to the  
34 department on or before January 1, 2003. The department  
35 shall make a single copy of the evaluation available at no  
36 cost to members of the public upon request. The  
37 department may recover the cost of additional copies that  
38 are requested. After holding a series of public hearings on  
39 the evaluation, the department shall submit a report,  
40 along with its own recommendations for continuing,



1 modifying, or terminating the independent review  
2 system and the independent health care  
3 ombudsprogram, to the Legislature by March 1, 2003. The  
4 department shall make a single copy of its report  
5 available at no cost to members of the public upon  
6 request. The department may recover the cost of  
7 additional copies that are requested.

8 1399.89. A plan's coverage decision regarding  
9 experimental or investigational therapies for individual  
10 enrollees shall be subject to this article.

11 1399.90. This article shall remain in effect only until  
12 January 1, 2004, and as of that date is repealed, unless a  
13 later enacted statute, that is enacted before January 1,  
14 2004, deletes or extends that date.

15 SEC. 10. No reimbursement is required by this act  
16 pursuant to Section 6 of Article XIII B of the California  
17 Constitution because the only costs that may be incurred  
18 by a local agency or school district will be incurred  
19 because this act creates a new crime or infraction,  
20 eliminates a crime or infraction, or changes the penalty  
21 for a crime or infraction, within the meaning of Section  
22 17556 of the Government Code, or changes the definition  
23 of a crime within the meaning of Section 6 of Article  
24 XIII B of the California Constitution.

25 Notwithstanding Section 17580 of the Government  
26 Code, unless otherwise specified, the provisions of this act  
27 shall become operative on the same date that the act  
28 takes effect pursuant to the California Constitution.

