

AMENDED IN ASSEMBLY SEPTEMBER 8, 1999

AMENDED IN ASSEMBLY SEPTEMBER 7, 1999

AMENDED IN ASSEMBLY AUGUST 16, 1999

AMENDED IN ASSEMBLY JULY 7, 1999

AMENDED IN SENATE MAY 28, 1999

AMENDED IN SENATE MAY 18, 1999

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**SENATE BILL**

**No. 189**

**Introduced by Senator Schiff** and Assembly Member  
Migden

**(Coauthors: Senators Chesbro, Karnette, Perata, and  
Rainey)**

(Coauthors: Assembly Members Alquist, ~~Baugh~~, Havice,  
Longville, ~~Margett~~, Romero, and Washington)

January 15, 1999

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An act to amend Section 1368.01 of, to amend, repeal, and add Sections 1368, 1368.03, 1368.04, and 1370.4 of, and to add Sections ~~1399.84 and 1399.86~~ *1374.34 and 1374.36* to, the Health and Safety Code, and to amend, repeal, and add Section 10145.3 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 189, as amended, Schiff. Health care coverage: grievances: independent medical review.

(1) 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 separately provides for the regulation of insurance, including disability insurance, administered by the Commissioner of Insurance.

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

This bill would revise this criteria to instead require that the enrollee or insured have a life-threatening, as defined, or seriously debilitating condition, as defined.

Existing law requires that the external, independent review of a health care service plan or disability insurer under these provisions meet certain criteria, including that the health care service plan or disability insurer contract with one or more impartial, independent, accredited entities which in turn are required to select an independent panel.

Existing law provides that the enrollee shall not be required to pay for the external, independent review and requires that the costs of the review be borne by the health care service plan or disability insurer.

This bill would require the Department of Corporations to contract with one or more impartial, independent, accredited entities for purposes of the external, independent review process, rather than the plan or insurer. The bill would require the plan or insurer to reimburse the department for costs associated with the contract.

(2) 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, 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.

(3) This bill would also include provisions which shall only become operative if AB 55 of the 1999–2000 Regular Session is enacted on or before December 31, 2000, and establishes a specified independent medical review system.

(4) 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. Section 1368 of the Health and Safety  
2 Code is amended to read:

3 1368. (a) Every plan shall do all of the following:

4 (1) Establish and maintain a grievance system  
5 approved by the department under which enrollees may  
6 submit their grievances to the plan. Each system shall  
7 provide reasonable procedures in accordance with  
8 department regulations that shall ensure adequate  
9 consideration of enrollee grievances and rectification  
10 when appropriate.

11 (2) Inform its subscribers and enrollees upon  
12 enrollment in the plan and annually thereafter of the  
13 procedure for processing and resolving grievances. The  
14 information shall include the location and telephone  
15 number where grievances may be submitted.

16 (3) Provide forms for grievances to be given to  
17 subscribers and enrollees who wish to register written  
18 grievances. The forms used by plans licensed pursuant to



1 Section 1353 shall be approved by the commissioner in  
2 advance as to format.

3 (4) Provide subscribers and enrollees with written  
4 responses to grievances, with a clear and concise  
5 explanation of the reasons for the plan's response. For  
6 grievances involving the delay, denial, or modification of  
7 health care services, the plan response shall describe the  
8 criteria used and the clinical reasons for its decision,  
9 including all criteria and clinical reasons related to  
10 medical necessity. If a plan, or one of its contracting  
11 providers, issues a determination delaying, denying, or  
12 modifying health care services based in whole or in part  
13 on a finding that the proposed health care services are not  
14 a covered benefit under the contract that applies to the  
15 enrollee, the decision shall clearly specify the provisions  
16 in the contract that exclude that coverage.

17 (5) Keep in its files all copies of grievances, and the  
18 responses thereto, for a period of five years.

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

32 (B) A grievance may be submitted to the department  
33 for review and resolution prior to any arbitration.

34 (C) Notwithstanding subparagraphs (A) and (B), the  
35 department may refer any grievance that does not  
36 pertain to compliance with this chapter to the State  
37 Department of Health Services, the California  
38 Department of Aging, the federal Health Care Financing  
39 Administration, or any other appropriate governmental  
40 entity for investigation and resolution.



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

16 (3) The department shall review the written  
17 documents submitted with the subscriber’s or the  
18 enrollee’s request for review, or submitted by the agent  
19 on behalf of the subscriber or enrollee. The department  
20 may ask for additional information, and may hold an  
21 informal meeting with the involved parties, including  
22 providers who have joined in submitting the grievance ,  
23 or who are otherwise assisting or advocating on behalf of  
24 the subscriber or enrollee.

25 (4) The department shall send a written notice of the  
26 final disposition of the grievance , and the reasons  
27 therefor, to the subscriber or enrollee, the agent, to any  
28 provider that has joined with or is otherwise assisting the  
29 subscriber or enrollee, and to the plan, within 30 calendar  
30 days of receipt of the request for review unless the  
31 commissioner, in his or her discretion, determines that  
32 additional time is reasonably necessary to fully and fairly  
33 evaluate the relevant grievance.

34 (5) Distribution of the written notice shall not be  
35 deemed a waiver of any exemption or privilege under  
36 existing law, including, but not limited to, Section 6254.5  
37 of the Government Code, for any information in  
38 connection with and including the written notice, nor  
39 shall any person employed or in any way retained by the



1 department be required to testify as to that information  
2 or notice.

3 (6) The commissioner shall establish and maintain a  
4 system of aging of grievances that are pending and  
5 unresolved for 30 days or more, that shall include a brief  
6 explanation of the reasons each grievance is pending and  
7 unresolved for 30 days or more.

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

22 (c) The plan's grievance system shall include a system  
23 of aging of grievances that are pending and unresolved  
24 for 30 days or more. The plan shall provide a quarterly  
25 report to the commissioner of grievances pending and  
26 unresolved for 30 or more days with separate categories  
27 of grievances for Medicare enrollees and Medi-Cal  
28 enrollees. The plan shall include with the report a brief  
29 explanation of the reasons each grievance is pending and  
30 unresolved for 30 days or more. The plan may include the  
31 following statement in the quarterly report that is made  
32 available to the public by the commissioner:

33  
34 "Under Medicare and Medi-Cal law, Medicare  
35 enrollees and Medi-Cal enrollees each have separate  
36 avenues of appeal that are not available to other  
37 enrollees. Therefore, grievances pending and  
38 unresolved may reflect enrollees pursuing their  
39 Medicare or Medi-Cal appeal rights."  
40



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

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

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

31 (f) Upon the operation of the Department of Managed  
32 Care and the appointment of its director, the  
33 responsibilities of the Department of Corporations and its  
34 commissioner shall be transferred to the Department of  
35 Managed Care and its director.

36 (g) If Assembly Bill 55 of the 1999–2000 Regular  
37 Session is enacted, this section shall remain in effect only  
38 until January 1, 2001, and as of that date is repealed, unless  
39 a later enacted statute, that is enacted before January 1,  
40 2001, deletes or extends that date.



1 SEC. 2. Section 1368 is added to the Health and Safety  
2 Code, to read:

3 1368. (a) Every plan shall do all of the following:

4 (1) Establish and maintain a grievance system  
5 approved by the department under which enrollees may  
6 submit their grievances to the plan. Each system shall  
7 provide reasonable procedures in accordance with  
8 department regulations that shall ensure adequate  
9 consideration of enrollee grievances and rectification  
10 when appropriate.

11 (2) Inform its subscribers and enrollees upon  
12 enrollment in the plan and annually thereafter of the  
13 procedure for processing and resolving grievances. The  
14 information shall include the location and telephone  
15 number where grievances may be submitted.

16 (3) Provide forms for grievances to be given to  
17 subscribers and enrollees who wish to register written  
18 grievances. The forms used by plans licensed pursuant to  
19 Section 1353 shall be approved by the director in advance  
20 as to format.

21 (4) Provide subscribers and enrollees with written  
22 responses to grievances, with a clear and concise  
23 explanation of the reasons for the plan's response. For  
24 grievances involving the delay, denial, or modification of  
25 health care services, the plan response shall describe the  
26 criteria used and the clinical reasons for its decision,  
27 including all criteria and clinical reasons related to  
28 medical necessity. If a plan, or one of its contracting  
29 providers, issues a decision delaying, denying, or  
30 modifying health care services based in whole or in part  
31 on a finding that the proposed health care services are not  
32 a covered benefit under the contract that applies to the  
33 enrollee, the decision shall clearly specify the provisions  
34 in the contract that exclude that coverage.

35 (5) Keep in its files all copies of grievances, and the  
36 responses thereto, for a period of five years.

37 (b) (1) (A) After either completing the grievance  
38 process described in subdivision (a), or participating in  
39 the process for at least 30 days, a subscriber or enrollee  
40 may submit the grievance to the department for review.



1 In any case determined by the department to be a case  
2 involving an imminent and serious threat to the health of  
3 the patient, including, but not limited to, severe pain, the  
4 potential loss of life, limb, or major bodily function, or in  
5 any other case where the department determines that an  
6 earlier review is warranted, a subscriber or enrollee shall  
7 not be required to complete the grievance process or  
8 participate in the process for at least 30 days before  
9 submitting a grievance to the department for review.

10 (B) A grievance may be submitted to the department  
11 for review and resolution prior to any arbitration.

12 (C) Notwithstanding subparagraphs (A) and (B), the  
13 department may refer any grievance that does not  
14 pertain to compliance with this chapter to the State  
15 Department of Health Services, the California  
16 Department of Aging, the federal Health Care Financing  
17 Administration, or any other appropriate governmental  
18 entity for investigation and resolution.

19 (2) If the subscriber or enrollee is a minor, or is  
20 incompetent or incapacitated, the parent, guardian,  
21 conservator, relative, or other designee of the subscriber  
22 or enrollee, as appropriate, may submit the grievance to  
23 the department as the agent of the subscriber or enrollee.  
24 Further, a provider may join with, or otherwise assist, a  
25 subscriber or enrollee, or the agent, to submit the  
26 grievance to the department. In addition, following  
27 submission of the grievance to the department, the  
28 subscriber or enrollee, or the agent, may authorize the  
29 provider to assist, including advocating on behalf of the  
30 subscriber or enrollee. For purposes of this section, a  
31 “relative” includes the parent, stepparent, spouse, adult  
32 son or daughter, grandparent, brother, sister, uncle, or  
33 aunt of the subscriber or enrollee.

34 (3) The department shall review the written  
35 documents submitted with the subscriber’s or the  
36 enrollee’s request for review, or submitted by the agent  
37 on behalf of the subscriber or enrollee. The department  
38 may ask for additional information, and may hold an  
39 informal meeting with the involved parties, including  
40 providers who have joined in submitting the grievance or



1 who are otherwise assisting or advocating on behalf of the  
2 subscriber or enrollee. If after reviewing the record, the  
3 department concludes that the grievance, in whole or in  
4 part, is eligible for review under the independent  
5 medical review system established pursuant to Article 12  
6 (commencing with Section ~~1399.80~~ 1374.30), the  
7 department shall immediately notify the subscriber or  
8 enrollee, or agent, of that option and shall, if requested  
9 orally or in writing, shall assist the subscriber or enrollee  
10 in participating in the independent medical review  
11 system.

12 (4) If after reviewing the record of a grievance, the  
13 department concludes that a health care service eligible  
14 for coverage and payment under a health care service  
15 plan contract has been delayed, denied, or modified by a  
16 plan, or by one of its contracting providers, in whole or in  
17 part due to a determination that the service is not  
18 medically necessary, and that determination was not  
19 communicated to the enrollee in writing along with a  
20 notice of the enrollee's potential right to participate in  
21 the independent medical review system, as required by  
22 this chapter, the director shall, by order, assess  
23 administrative penalties. A proceeding for the issuance of  
24 an order assessing administrative penalties shall be  
25 subject to appropriate notice of, and the opportunity for,  
26 a hearing with regard to the person affected in  
27 accordance with Section 1397. The administrative  
28 penalties shall not be deemed an exclusive remedy  
29 available to the director. These penalties shall be paid to  
30 the State Managed Care Fund.

31 (5) The department shall send a written notice of the  
32 final disposition of the grievance, and the reasons  
33 therefor, to the subscriber or enrollee, the agent, to any  
34 provider that has joined with or is otherwise assisting the  
35 subscriber or enrollee, and to the plan, within 30 calendar  
36 days of receipt of the request for review unless the  
37 director, in his or her discretion, determines that  
38 additional time is reasonably necessary to fully and fairly  
39 evaluate the relevant grievance. In any case not eligible  
40 for the independent medical review system established



1 pursuant to Article 12 (commencing with Section ~~1399.80~~  
2 *1374.30*), the department's written notice shall include, at  
3 a minimum, the following:

4 (A) A summary of its findings and the reasons why the  
5 department found the plan to be, or not to be, in  
6 compliance with any applicable laws, regulations, or  
7 orders of the director.

8 (B) A discussion of the department's contact with any  
9 medical provider, or any other independent expert relied  
10 on by the department, along with a summary of the views  
11 and qualifications of that provider or expert.

12 (C) If the enrollee's grievance is sustained in whole or  
13 part, information about any corrective action taken.

14 (6) In any department review of a grievance involving  
15 a disputed health care service, as defined in subdivision  
16 (b) of Section ~~1399.80~~ *1374.30*, that is not eligible for the  
17 independent medical review system established  
18 pursuant to Article 12 (commencing with Section  
19 ~~1399.80~~ *1374.30*), in which the department finds that the  
20 plan has delayed, denied, or modified health care services  
21 that are medically necessary, based on the specific  
22 medical circumstances of the enrollee, and those services  
23 are a covered benefit under the terms and conditions of  
24 the health care service plan contract, the department's  
25 written notice shall either: (A) Order the plan to  
26 promptly offer and provide those health care services to  
27 the enrollee, or (B) Order the plan to promptly  
28 reimburse the enrollee for any reasonable costs associated  
29 with urgent care or emergency services, or other  
30 extraordinary and compelling health care services, when  
31 the department finds that the enrollee's decision to  
32 secure those services outside of the plan network was  
33 reasonable under the circumstances. The department's  
34 order shall be binding on the plan.

35 (7) Distribution of the written notice shall not be  
36 deemed a waiver of any exemption or privilege under  
37 existing law, including, but not limited to, Section 6254.5  
38 of the Government Code, for any information in  
39 connection with and including the written notice, nor  
40 shall any person employed or in any way retained by the



1 department be required to testify as to that information  
2 or notice.

3 (8) The director shall establish and maintain a system  
4 of aging of grievances that are pending and unresolved  
5 for 30 days or more, that shall include a brief explanation  
6 of the reasons each grievance is pending and unresolved  
7 for 30 days or more.

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

22 (c) The plan's grievance system shall include a system  
23 of aging of grievances that are pending and unresolved  
24 for 30 days or more. The plan shall provide a quarterly  
25 report to the director of grievances pending and  
26 unresolved for 30 or more days with separate categories  
27 of grievances for Medicare enrollees and Medi-Cal  
28 enrollees. The plan shall include with the report a brief  
29 explanation of the reasons each grievance is pending and  
30 unresolved for 30 days or more. The plan may include the  
31 following statement in the quarterly report that is made  
32 available to the public by the director:

33

34 "Under Medicare and Medi-Cal law, Medicare  
35 enrollees and Medi-Cal enrollees each have separate  
36 avenues of appeal that are not available to other  
37 enrollees. Therefore, grievances pending and  
38 unresolved may reflect enrollees pursuing their  
39 Medicare or Medi-Cal appeal rights."

40



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

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

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

31 (f) This section shall become operative on January 1,  
32 2001, and then only if Assembly Bill 55 of the 1999–2000  
33 Regular Session is enacted.

34 SEC. 3. Section 1368.01 of the Health and Safety Code  
35 is amended to read:

36 1368.01. (a) The grievance system shall require the  
37 plan to resolve grievances within 30 days.

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 three days from receipt of  
11 the grievance.

12 SEC. 4. 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 30 days before pursuing a grievance  
17 through the department. However, the department may  
18 not impose this waiting period for expedited review cases  
19 covered by subdivision (b) of Section 1368.01 or in any  
20 other case where the department determines that an  
21 earlier review is warranted.

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

29 (c) Upon the operation of the Department of  
30 Managed Care, the responsibilities of the Department of  
31 Corporations pursuant to this section shall be transferred  
32 to the Department of Managed Care.

33 (d) If Assembly Bill 55 of the 1999–2000 Regular  
34 Session is enacted, this section shall remain in effect only  
35 until January 1, 2001, and as of that date is repealed, unless  
36 a later enacted statute, that is enacted before January 1,  
37 2001, deletes or extends that date.

38 SEC. 5. Section 1368.03 is added to the Health and  
39 Safety Code, to read:



1 1368.03. (a) The department may require enrollees  
2 and subscribers to participate in a plan's grievance  
3 process for up to 30 days before pursuing a grievance  
4 through the department or the independent medical  
5 review system. However, the department may not  
6 impose this waiting period for expedited review cases  
7 covered by subdivision (b) of Section 1368.01 or in any  
8 other case where the department determines that an  
9 earlier review is warranted.

10 (b) Notwithstanding subdivision (a), the department  
11 may refer any grievance issue that does not pertain to  
12 compliance with this chapter to the State Department of  
13 Health Services, the California Department of Aging, the  
14 federal Health Care Financing Administration, or any  
15 other appropriate governmental entity for investigation  
16 and resolution.

17 (c) This section shall become operative on January 1,  
18 2001, and then only if Assembly Bill 55 of the 1999–2000  
19 Regular Session is enacted.

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

22 1368.04. (a) The commissioner shall investigate and  
23 take enforcement action against plans regarding  
24 grievances reviewed and found by the department to  
25 involve plan noncompliance with the requirements of  
26 this chapter. The commissioner shall periodically  
27 evaluate grievances to determine if any audit,  
28 investigative, or enforcement actions should be  
29 undertaken by the department.

30 (b) The commissioner may, after appropriate notice  
31 and opportunity for hearing in accordance with Section  
32 1397, by order, assess administrative penalties, if the  
33 commissioner determines that a health care service plan  
34 has knowingly committed, or has performed with a  
35 frequency that indicates a general business practice, any  
36 of the following:

37 (1) Repeated failure to act promptly and reasonably to  
38 investigate and resolve grievances in accordance with  
39 Section 1368.01.



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

4 (c) The administrative penalties available to the  
5 commissioner pursuant to this section are not exclusive,  
6 and may be sought and employed in any combination  
7 with civil, criminal, and other administrative remedies  
8 deemed warranted by the commissioner to enforce this  
9 chapter.

10 (d) The administrative penalties authorized pursuant  
11 to this section shall be paid to the State Corporations  
12 Fund.

13 (e) Upon the operation of the Department of  
14 Managed Care and the appointment of its director, the  
15 responsibilities of the Department of Corporations and its  
16 commissioner shall be transferred to the Department of  
17 Managed Care and its director.

18 (f) If Assembly Bill 55 of the 1999–2000 Regular Session  
19 is enacted, this section shall remain in effect only until  
20 January 1, 2001, and as of that date is repealed, unless a  
21 later enacted statute, that is enacted before January 1,  
22 2001, deletes or extends that date.

23 SEC. 7. Section 1368.04 is added to the Health and  
24 Safety Code, to read:

25 1368.04. (a) The director shall investigate and take  
26 enforcement action against plans regarding grievances  
27 reviewed and found by the department to involve  
28 noncompliance with the requirements of this chapter,  
29 including grievances that have been reviewed pursuant  
30 to the independent medical review system established  
31 pursuant to Article 12 (commencing with Section  
32 ~~1399.80~~ 1374.30). Where substantial harm to an enrollee  
33 has occurred as a result of plan noncompliance, the  
34 director shall, by order, assess administrative penalties  
35 subject to appropriate notice of, and the opportunity for,  
36 a hearing with regard to the person affected in  
37 accordance with Section 1397. The administrative  
38 penalties shall not be deemed an exclusive remedy  
39 available to the director. These penalties shall be paid to  
40 the State Managed Care Fund. The director shall



1 periodically evaluate grievances to determine if any  
2 audit, investigative, or enforcement actions should be  
3 undertaken by the department.

4 (b) The director may, after appropriate notice and  
5 opportunity for hearing in accordance with Section 1397,  
6 by order, assess administrative penalties if the director  
7 determines that a health care service plan has knowingly  
8 committed, or has performed with a frequency that  
9 indicates a general business practice, either of the  
10 following:

11 (1) Repeated failure to act promptly and reasonably to  
12 investigate and resolve grievances in accordance with  
13 Section 1368.01.

14 (2) Repeated failure to act promptly and reasonably to  
15 resolve grievances when the obligation of the plan to the  
16 enrollee or subscriber is reasonably clear.

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

23 (d) The administrative penalties authorized pursuant  
24 to this section shall be paid to the State Managed Care  
25 Fund.

26 (e) This section shall become operative on January 1,  
27 2001, and then only if Assembly Bill 55 of the 1999–2000  
28 Regular Session is enacted.

29 SEC. 8. 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) (A) The enrollee has a life-threatening or  
37 seriously debilitating condition.

38 (B) For purposes of this section, "life-threatening"  
39 means either or both of the following:



1 (i) Diseases or conditions where the likelihood of  
2 death is high unless the course of the disease is  
3 interrupted.

4 (ii) Diseases or conditions with potentially fatal  
5 outcomes, where the end point of clinical intervention is  
6 survival.

7 (C) For purposes of this section, “seriously  
8 debilitating” means diseases or conditions that cause  
9 major irreversible morbidity.

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

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

38 (4) The enrollee has been denied coverage by the plan  
39 for a drug, device, procedure or other therapy  
40 recommended or requested pursuant to paragraph (3).



1 (5) The specific drug, device, procedure or other  
2 therapy recommended pursuant to paragraph (3) would  
3 be a covered service, except for the plan's determination  
4 that the therapy is experimental or investigational.

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

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

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

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

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

40 (A) The plan.



1 (B) Any officer, director, or management employee of  
2 the plan.

3 (C) The physician, the physician's medical group, or  
4 the independent practice association (IPA) proposing  
5 the therapy.

6 (D) The institution at which the therapy would be  
7 provided.

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

11 (4) For purposes of this section, the following terms  
12 have the following meanings:

13 (A) "Material familial affiliation" means any  
14 relationship as a spouse, child, parent, sibling, spouse's  
15 parent, or child's spouse.

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

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

36 (5) The enrollee shall not be required to pay for the  
37 external, independent review. The costs of the review  
38 shall be borne by the plan. The plan shall reimburse the  
39 department for any costs associated with contracting with  
40 any independent entity pursuant to paragraph (2).



1 (6) The plan shall provide to the independent entity  
2 arranging for the panel of experts a copy of the following  
3 documents within five business days of the plan's receipt  
4 of a request by an enrollee or enrollee's physician for an  
5 external, independent review:

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

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

24 (C) Any information submitted by the enrollee or the  
25 enrollee's physician to the plan in support of the  
26 enrollee's request for coverage of the proposed drug,  
27 device, procedure, or other therapy.

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

39 (8) Each expert's analysis and recommendation shall  
40 be in written form and state the reasons the requested



1 therapy is or is not likely to be more beneficial for the  
2 enrollee than any available standard therapy, and the  
3 reasons that the expert recommends that the therapy  
4 should or should not be provided by the plan, citing the  
5 enrollee's specific medical condition, the relevant  
6 documents provided pursuant to paragraph (6), and the  
7 relevant medical and scientific evidence, including, but  
8 not limited to, the medical and scientific evidence as  
9 defined in subdivision (d), to support the expert's  
10 recommendation.

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

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

39 (11) The plan shall have written policies describing  
40 the external, independent review process. The plan shall



1 disclose the availability of the external, independent  
2 review process and how enrollees may access the review  
3 process in the plan's evidence of coverage and disclosure  
4 forms.

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

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

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

36 (2) Peer-reviewed literature, biomedical compendia,  
37 and other medical literature that meet the criteria of the  
38 National Institutes of Health's National Library of  
39 Medicine for indexing in Index Medicus, Excerpta  
40 Medicus (EMBASE), Medline, and MEDLARS data base



1 Health Services Technology Assessment Research  
2 (HSTAR).

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

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

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

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

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

28 (1) The independent entity shall be an organization  
29 that has as its primary function the provision of expert  
30 reviews and related services and receives a majority of its  
31 revenues from these services, except that an academic  
32 medical center may qualify as an independent entity for  
33 purposes of this act without meeting either of these  
34 criteria. 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 shall 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 shall 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, 2000.

34 (h) Upon the operation of the Department of  
35 Managed Care and the appointment of its director, the  
36 responsibilities of the Department of Corporations and its  
37 commissioner shall be transferred to the Department of  
38 Managed Care and its director.

39 (i) If Assembly Bill 55 of the 1999–2000 Regular Session  
40 is enacted, this section shall remain in effect only until



1 January 1, 2001, and as of that date is repealed, unless a  
2 later enacted statute, that is enacted before January 1,  
3 2001, deletes or extends that date.

4 SEC. 9. Section 1370.4 is added to the Health and  
5 Safety Code, to read:

6 1370.4. (a) Every health care service plan shall  
7 provide an external, independent review process to  
8 examine the plan's coverage decisions regarding  
9 experimental or investigational therapies for individual  
10 enrollees who meet all of the following criteria:

11 (1) (A) The enrollee has a life-threatening or  
12 seriously debilitating condition.

13 (B) For purposes of this section, "life-threatening"  
14 means either or both of the following:

15 (i) Diseases or conditions where the likelihood of  
16 death is high unless the course of the disease is  
17 interrupted.

18 (ii) Diseases or conditions with potentially fatal  
19 outcomes, where the end point of clinical intervention is  
20 survival.

21 (C) For purposes of this section, "seriously  
22 debilitating" means diseases or conditions that cause  
23 major irreversible morbidity.

24 (2) The enrollee's physician certifies that the enrollee  
25 has a condition, as defined in paragraph (1), for which  
26 standard therapies have not been effective in improving  
27 the condition of the enrollee, for which standard  
28 therapies would not be medically appropriate for the  
29 enrollee, or for which there is no more beneficial standard  
30 therapy covered by the plan than the therapy proposed  
31 pursuant to paragraph (3).

32 (3) Either (A) the enrollee's physician, who is under  
33 contract with or employed by the plan, has  
34 recommended a drug, device, procedure or other  
35 therapy that the physician certifies in writing is likely to  
36 be more beneficial to the enrollee than any available  
37 standard therapies, or (B) the enrollee, or the enrollee's  
38 physician who is a licensed, board-certified or  
39 board-eligible physician qualified to practice in the area  
40 of practice appropriate to treat the enrollee's condition,



1 has requested a therapy that, based on two documents  
2 from the medical and scientific evidence, as defined in  
3 subdivision (d), is likely to be more beneficial for the  
4 enrollee than any available standard therapy. The  
5 physician certification pursuant to this subdivision shall  
6 include a statement of the evidence relied upon by the  
7 physician in certifying his or her recommendation.  
8 Nothing in this subdivision shall be construed to require  
9 the plan to pay for the services of a nonparticipating  
10 physician provided pursuant to this subdivision, that are  
11 not otherwise covered pursuant to the plan contract.

12 (4) The enrollee has been denied coverage by the plan  
13 for a drug, device, procedure, or other therapy  
14 recommended or requested pursuant to paragraph (3).

15 (5) The specific drug, device, procedure, or other  
16 therapy recommended pursuant to paragraph (3) would  
17 be a covered service, except for the plan's determination  
18 that the therapy is experimental or investigational.

19 (b) The plan's decision to delay, deny, or modify  
20 experimental or investigational therapies shall be subject  
21 to the independent medical review process under Article  
22 12 (commencing with Section ~~1399.80~~ 1374.30) of this  
23 chapter except that, in lieu of the information specified  
24 in subdivision (i) of Section ~~1399.80~~ 1374.30, an  
25 independent medical reviewer shall base his or her  
26 determination on relevant medical and scientific  
27 evidence, including, but not limited to, the medical and  
28 scientific evidence defined in subdivision (d).

29 (c) The independent medical review process shall also  
30 meet the following criteria:

31 (1) The plan shall notify eligible enrollees in writing of  
32 the opportunity to request the external independent  
33 review within five business days of the decision to deny  
34 coverage.

35 (2) If the enrollee's physician determines that the  
36 proposed therapy would be significantly less effective if  
37 not promptly initiated, the analyses and  
38 recommendations of the experts on the panel shall be  
39 rendered within seven days of the request for expedited  
40 review. At the request of the expert, the deadline shall be



1 extended by up to three days for a delay in providing the  
2 documents required. The timeframes specified in this  
3 paragraph shall be in addition to any otherwise applicable  
4 timeframes contained in subdivision (c) of Section  
5 ~~1399.83~~ 1374.33.

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

17 (4) Coverage for the services required under this  
18 section shall be provided subject to the terms and  
19 conditions generally applicable to other benefits under  
20 the plan contract.

21 (d) For the purposes of subdivision (b), "medical and  
22 scientific evidence" means the following sources:

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

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

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

39 (4) The following standard reference compendia: The  
40 American Hospital Formulary Service-Drug



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

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

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

18 (e) The independent review process established by  
19 this section shall be required on and after January 1, 2001.

20 (f) This section shall become operative on January 1,  
21 2001, and then only if Assembly Bill 55 of the 1999–2000  
22 Regular Session is enacted.

23 SEC. 10. Section ~~1399.84~~ 1374.34 is added to the  
24 Health and Safety Code, to read:

25 ~~1399.84.—~~

26 13933. (a) Upon receiving the decision adopted by  
27 the director pursuant to Section ~~1399.83~~ 1374.33 that a  
28 disputed health care service is medically necessary, the  
29 plan shall immediately contact the enrollee and offer to  
30 promptly implement the decision.

31 (b) A plan shall not engage in any conduct that has the  
32 effect of prolonging the independent review process. The  
33 engaging in that conduct or the failure of the plan to  
34 promptly implement the decision is a violation of this  
35 chapter and, in addition to any other fines, penalties, and  
36 other remedies available to the director under this  
37 chapter, the plan shall be subject to an administrative  
38 penalty of not less than five thousand dollars (\$5,000) for  
39 each day that the decision is not implemented.



1 Administrative penalties shall be deposited in the State  
2 Managed Care Fund.

3 (c) In any case where an enrollee secured urgent care;  
4 ~~emergency services, or other extraordinary and~~  
5 ~~compelling health care services outside of the plan or~~  
6 ~~emergency services outside of the plan~~ provider network,  
7 which services are later found by the independent  
8 medical review organization to have been medically  
9 necessary pursuant to Section ~~1399.83~~ 1374.33, the  
10 director shall require the plan to promptly reimburse the  
11 enrollee for any reasonable costs associated with those  
12 services when the director finds that the enrollee's  
13 decision to secure the services outside of the plan  
14 provider network prior to completing the plan grievance  
15 process or seeking an independent medical review was  
16 reasonable under the circumstances and the disputed  
17 health care services were a covered benefit under the  
18 terms and conditions of the health care service plan  
19 contract.

20 (d) In addition to requiring plan compliance  
21 regarding subdivisions (a), (b), and (c) the director shall  
22 review individual cases submitted for independent  
23 medical review to determine whether any enforcement  
24 actions, including penalties, may be appropriate. In  
25 particular, where substantial harm to an enrollee has  
26 already occurred because of the decision of a plan, or one  
27 of its contracting providers, to delay, deny, or modify  
28 covered health care services that an independent  
29 medical review determines to be medically necessary  
30 pursuant to Section ~~1399.83~~ 1374.33, the director shall  
31 impose penalties.

32 (e) Pursuant to Section 1368.04, the director shall  
33 perform an annual audit of independent medical review  
34 cases for the dual purposes of education and the  
35 opportunity to determine if any investigative or  
36 enforcement actions should be undertaken by the  
37 department, particularly if a plan repeatedly fails to act  
38 promptly and reasonably to resolve grievances associated  
39 with a delay, denial, or modification of medically  
40 necessary health care services when the obligation of the



1 plan to provide those health care services to enrollees or  
2 subscribers is reasonably clear.

3 (f) This section shall become operative on January 1,  
4 2001, and then only if Assembly Bill 55 of the 1999-2000  
5 Regular Session is enacted.

6 SEC. 11. Section ~~1399.86~~ 1374.36 is added to the  
7 Health and Safety Code, to read:

8 ~~1399.86.—~~

9 1374.36. (a) The director shall submit to the  
10 Legislature by March 1, 2002, a report on the initial  
11 implementation of this article. The report shall include a  
12 description of assessments imposed on plans to  
13 implement this article, increased staffing and other  
14 resources attributable to these new responsibilities, and  
15 any redirection of existing staff and resources to carry out  
16 these responsibilities. A single copy of the report shall be  
17 made available at no cost to members of the public upon  
18 request. The department may recover the cost of  
19 additional copies that are requested.

20 (b) This section shall become operative on January 1,  
21 2001, and then only if Assembly Bill 55 of the 1999-2000  
22 Regular Session is enacted.

23 SEC. 12. Section 10145.3 of the Insurance Code is  
24 amended to read:

25 10145.3. (a) Every disability insurer that covers  
26 hospital, medical, or surgical benefits shall provide an  
27 external, independent review process to examine the  
28 insurer's coverage decisions regarding experimental or  
29 investigational therapies for individual insureds who  
30 meet all of the following criteria:

31 (1) (A) The insured has a life-threatening or seriously  
32 debilitating condition.

33 (B) For purposes of this section, "life-threatening"  
34 means either or both of the following:

35 (i) Diseases or conditions where the likelihood of  
36 death is high unless the course of the disease is  
37 interrupted.

38 (ii) Diseases or conditions with potentially fatal  
39 outcomes, where the end point of clinical intervention is  
40 survival.



1 (C) For purposes of this section, “seriously  
2 debilitating” means diseases or conditions that cause  
3 major irreversible morbidity.

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

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

31 (4) The insured has been denied coverage by the  
32 insurer for a drug, device, procedure, or other therapy  
33 recommended or requested pursuant to paragraph (3),  
34 unless coverage for the specific therapy has been  
35 excluded by the insurer’s contract.

36 (5) This section does not apply to any Medi-Cal  
37 beneficiary enrolled with an insurer under the insurer’s  
38 contract with the Medi-Cal program.

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



1 be a covered service except for the insurer's  
2 determination that the therapy is experimental or under  
3 investigation.

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

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

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

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

37 (A) The insurer.

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



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

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

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

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

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

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

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

34 (5) The insured shall not be required to pay for the  
35 external independent review. The costs of the review  
36 shall be borne by the insurer. The insurer shall reimburse  
37 the Department of Corporations for any costs associated  
38 with contracting with any independent entity pursuant  
39 to paragraph (2).



1 (6) The insurer shall provide to the independent  
2 entity arranging for the panel of experts a copy of the  
3 following documents within five business days of the  
4 insurer's receipt of a request by an insured or insured's  
5 physician for an external independent review.

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

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

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

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

39 (8) Each expert's analysis and recommendation shall  
40 be in written form and state the reasons the requested



1 therapy is or is not likely to be more beneficial for the  
2 insured than any available standard therapy, and the  
3 reasons that the expert recommends that the therapy  
4 should or should not be covered by the insurer, citing the  
5 insured's specific medical condition, the relevant  
6 documents provided pursuant to paragraph (6), and the  
7 relevant medical and scientific evidence, including, but  
8 not limited to, the medical and scientific evidence as  
9 defined in subdivision (d), to support the expert's  
10 recommendation.

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

26 (10) If the majority of experts on the panel  
27 recommend providing the proposed therapy, pursuant to  
28 paragraph (8), the recommendation shall be binding on  
29 the insurer. If the recommendations of the experts on the  
30 panel are evenly divided as to whether the therapy  
31 should be provided, then the panel's decision shall be  
32 deemed to be in favor of coverage. If less than a majority  
33 of the experts on the panel recommend providing the  
34 therapy, the insurer is not required to provide the  
35 therapy. Coverage for the services required under this  
36 section shall be provided subject to the terms and  
37 conditions generally applicable to other benefits under  
38 the contract.

39 (11) The insurer shall have written policies describing  
40 the external, independent review process. The insurer



1 shall disclose the availability of the external, independent  
2 review process and how insureds may access the review  
3 process in the insurer's evidence of coverage and  
4 disclosure forms.

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

28 (d) For the purposes of paragraph (3) of subdivision  
29 (a), "medical and scientific evidence" means the  
30 following sources:

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

37 (2) Peer-reviewed literature, biomedical compendia  
38 and other medical literature that meet the criteria of the  
39 National Institutes of Health's National Library of  
40 Medicine for indexing in Index Medicus, Excerpta



1 Medicus (EMBASE), Medline and MEDLARS data base  
2 Health Services Technology Assessment Research  
3 (HSTAR).

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

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

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

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

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

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

39 (2) The independent entity shall submit to the  
40 accrediting organization and to the Department of



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

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

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

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

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

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

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

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

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

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

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



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

4 (A) Ensures that the experts retained are  
5 appropriately credentialed and privileged.

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

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

14 (D) Ensures the confidentiality of medical records  
15 and the review materials, consistent with the  
16 requirements of this section.

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

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

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

35 (g) The independent review process established by  
36 this section shall be required on and after January 1, 2000.

37 (h) Upon the operation of the Department of  
38 Managed Care and the appointment of its director, the  
39 responsibilities of the Department of Insurance and its



1 commissioner shall be transferred to the Department of  
2 Managed Care and its director.

3 (i) This section shall remain in effect only until the  
4 operative date of the independent review process  
5 established by Assembly Bill 55 of the 1999–2000 Regular  
6 Session, and as of that date is repealed.

7 SEC. 13. Section 10145.3 is added to the Insurance  
8 Code, to read:

9 10145.3. (a) Every disability insurer that covers  
10 hospital, medical, or surgical benefits shall provide an  
11 external, independent review process to examine the  
12 insurer’s coverage decisions regarding experimental or  
13 investigational therapies for individual insureds who  
14 meet all of the following criteria:

15 (1) (A) The insured has a life-threatening or seriously  
16 debilitating condition.

17 (B) For purposes of this section, “life-threatening”  
18 means either or both of the following:

19 (i) Diseases or conditions where the likelihood of  
20 death is high unless the course of the disease is  
21 interrupted.

22 (ii) Diseases or conditions with potentially fatal  
23 outcomes, where the end point of clinical intervention is  
24 survival.

25 (C) For purposes of this section, “seriously  
26 debilitating” means diseases or conditions that cause  
27 major irreversible morbidity.

28 (2) The insured’s physician certifies that the insured  
29 has a condition, as defined in paragraph (1), for which  
30 standard therapies have not been effective in improving  
31 the condition of the insured, for which standard therapies  
32 would not be medically appropriate for the insured, or for  
33 which there is no more beneficial standard therapy  
34 covered by the insurer than the therapy proposed  
35 pursuant to paragraph (3).

36 (3) Either (A) the insured’s contracting physician has  
37 recommended a drug, device, procedure, or other  
38 therapy that the physician certifies in writing is likely to  
39 be more beneficial to the insured than any available  
40 standard therapies, or (B) the insured, or the insured’s



1 physician who is a licensed, board-certified or  
2 board-eligible physician qualified to practice in the area  
3 of practice appropriate to treat the insured's condition,  
4 has requested a therapy that, based on two documents  
5 from the medical and scientific evidence, as defined in  
6 subdivision (d), is likely to be more beneficial for the  
7 insured than any available standard therapy. The  
8 physician certification pursuant to this subdivision shall  
9 include a statement of the evidence relied upon by the  
10 physician in certifying his or her recommendation.  
11 Nothing in this subdivision shall be construed to require  
12 the insurer to pay for the services of a noncontracting  
13 physician, provided pursuant to this subdivision, that are  
14 not otherwise covered pursuant to the contract.

15 (4) The insured has been denied coverage by the  
16 insurer for a drug, device, procedure, or other therapy  
17 recommended or requested pursuant to paragraph (3),  
18 unless coverage for the specific therapy has been  
19 excluded by the insurer's contract.

20 (5) The specific drug, device, procedure, or other  
21 therapy recommended pursuant to paragraph (3) would  
22 be a covered service except for the insurer's  
23 determination that the therapy is experimental or under  
24 investigation.

25 (b) The insurer's decision to deny, delay, or modify  
26 experimental or investigational therapies shall be subject  
27 to the independent medical review process established  
28 under Article 12 (commencing with Section ~~1399.80~~  
29 *1374.30*) of Chapter 2 of Division 2 of the Health and  
30 Safety Code, except that in lieu of the information  
31 specified in subdivision (i) of Section ~~1399.80~~ *1374.30*, an  
32 independent medical reviewer shall base his or her  
33 determination on relevant medical and scientific  
34 evidence, including, but not limited to, the medical and  
35 scientific evidence defined in subdivision (d).

36 (c) The independent medical review process shall also  
37 meet the following criteria:

38 (1) The insurer shall notify eligible insureds in writing  
39 of the opportunity to request the external independent



1 review within five business days of the decision to deny  
2 coverage.

3 (2) If the insured's physician determines that the  
4 proposed therapy would be significantly less effective if  
5 not promptly initiated, the analyses and  
6 recommendations of the experts on the panel shall be  
7 rendered within seven days of the request for expedited  
8 review. At the request of the expert, the deadline shall be  
9 extended by up to three days for a delay in providing the  
10 documents required. The timeframes specified in this  
11 paragraph shall be in addition to any otherwise applicable  
12 timeframes contained in subdivision (c) of Section  
13 ~~1399.83~~ 1374.33 of the Health and Safety Code.

14 (3) Each expert's analysis and recommendation shall  
15 be in written form and state the reasons the requested  
16 therapy is or is not likely to be more beneficial for the  
17 insured than any available standard therapy, and the  
18 reasons that the expert recommends that the therapy  
19 should or should not be covered by the insurer, citing the  
20 insured's specific medical condition, the relevant  
21 documents, and the relevant medical and scientific  
22 evidence, including, but not limited to, the medical and  
23 scientific evidence as defined in subdivision (d), to  
24 support the expert's recommendation.

25 (4) Coverage for the services required under this  
26 section shall be provided subject to the terms and  
27 conditions generally applicable to other benefits under  
28 the contract.

29 (d) For the purposes of subdivision (b), "medical and  
30 scientific evidence" means the following sources:

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

37 (2) Peer-reviewed literature, biomedical compendia  
38 and other medical literature that meet the criteria of the  
39 National Institutes of Health's National Library of  
40 Medicine for indexing in Index Medicus, Excerpta



1 Medicus (EMBASE), Medline and MEDLARS data base  
2 Health Services Technology Assessment Research  
3 (HSTAR).

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

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

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

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

26 (e) The independent review process established by  
27 this section shall be required on and after January 1, 2001.

28 (f) This section shall become operative on January 1,  
29 2001, and then only if Assembly Bill 55 of the 1999–2000  
30 Regular Session is enacted.

31 SEC. 14. No reimbursement is required by this act  
32 pursuant to Section 6 of Article XIII B of the California  
33 Constitution because the only costs that may be incurred  
34 by a local agency or school district will be incurred  
35 because this act creates a new crime or infraction,  
36 eliminates a crime or infraction, or changes the penalty  
37 for a crime or infraction, within the meaning of Section  
38 17556 of the Government Code, or changes the definition



- 1 of a crime within the meaning of Section 6 of Article
- 2 XIII B of the California Constitution.

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