Senate Bill No. 189

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Passed the Senate September 10, 1999

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Secretary of the Senate

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Passed the Assembly September 9, 1999

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Chief Clerk of the Assembly

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This bill was received by the Governor this _____ day

of _____, 1999, at _____ o'clock ____M.

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Private Secretary of the Governor

CHAPTER _____

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 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, 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 or seriously debilitating condition.

(2) 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.

(3) 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.

(4) 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.

(5) 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.

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

SECTION 1. Section 1368 of the Health and Safety Code is amended to read:

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

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

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

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

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

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

(b) (1) (A) After either completing the grievance process described in subdivision (a), or participating in

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

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

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

(2) If the subscriber or enrollee is a minor, or is incompetent or incapacitated, the parent, guardian, conservator, relative, or other designee of the subscriber or enrollee, as appropriate, may submit the grievance to the department as the agent of the subscriber or enrollee. Further, a provider may join with, or otherwise assist, a subscriber or enrollee, or the agent, to submit the grievance to the department. In addition, following submission of the grievance to the department, the subscriber or enrollee, or the agent, may authorize the provider to assist, including advocating on behalf of the subscriber or enrollee. For purposes of this section, a ‘‘relative’’ includes the parent, stepparent, spouse, adult son or daughter, grandparent, brother, sister, uncle, or aunt of the subscriber or enrollee.

(3) The department shall review the written documents submitted with the subscriber’s or the enrollee’s request for review, or submitted by the agent on behalf of the subscriber or enrollee. The department may ask for additional information, and may hold an

informal meeting with the involved parties, including providers who have joined in submitting the grievance, or who are otherwise assisting or advocating on behalf of the subscriber or enrollee.

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

(5) Distribution of the written notice shall not be deemed a waiver of any exemption or privilege under existing law, including, but not limited to, Section 6254.5 of the Government Code, for any information in connection with and including the written notice, nor shall any person employed or in any way retained by the department be required to testify as to that information or notice.

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

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

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

> ''Under Medicare and Medi-Cal law, Medicare enrollees and Medi-Cal enrollees each have separate avenues of appeal that are not available to other enrollees. Therefore, grievances pending and unresolved may reflect enrollees pursuing their Medicare or Medi-Cal appeal rights.''

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) If the subscriber or enrollee is a minor, or is incompetent or incapacitated, the parent, guardian,

conservator, relative, or other designee of the subscriber or enrollee, as appropriate, may submit the grievance to the department as the agent of the subscriber or enrollee. Further, a provider may join with, or otherwise assist, a subscriber or enrollee, or the agent, to submit the grievance to the department. In addition, following submission of the grievance to the department, the subscriber or enrollee, or the agent, may authorize the provider to assist, including advocating on behalf of the subscriber or enrollee. For purposes of this section, a ''relative'' includes the parent, stepparent, spouse, adult son or daughter, grandparent, brother, sister, uncle, or aunt of the subscriber or enrollee.

(3) The department shall review the written documents submitted with the subscriber's or the enrollee's request for review, or submitted by the agent on behalf of the subscriber or enrollee. The department may ask for additional information, and may hold an informal meeting with the involved parties, including providers who have joined in submitting the grievance or who are otherwise assisting or advocating on behalf of the subscriber or enrollee. If after reviewing the record, the department concludes that the grievance, in whole or in part, is eligible for review under the independent medical review system established pursuant to Article 12 (commencing with Section 1374.30), the department shall immediately notify the subscriber or enrollee, or agent, of that option and shall, if requested orally or in writing, shall assist the subscriber or enrollee in participating in the independent medical review system.

(4) If after reviewing the record of a grievance, the department concludes that a health care service eligible for coverage and payment under a health care service plan contract has been delayed, denied, or modified by a plan, or by one of its contracting providers, in whole or in part due to a determination that the service is not medically necessary, and that determination was not communicated to the enrollee in writing along with a notice of the enrollee's potential right to participate in the independent medical review system, as required by

this chapter, the director shall, by order, assess administrative penalties. A proceeding for the issuance of an order assessing administrative penalties shall be subject to appropriate notice of, and the opportunity for, a hearing with regard to the person affected in accordance with Section 1397. The administrative penalties shall not be deemed an exclusive remedy available to the director. These penalties shall be paid to the State Managed Care Fund.

(5) The department shall send a written notice of the final disposition of the grievance, and the reasons therefor, to the subscriber or enrollee, the agent, to any provider that has joined with or is otherwise assisting the subscriber or enrollee, and to the plan, within 30 calendar days of receipt of the request for review unless the director, in his or her discretion, determines that additional time is reasonably necessary to fully and fairly evaluate the relevant grievance. In any case not eligible for the independent medical review system established pursuant to Article 12 (commencing with Section 1374.30), the department's written notice shall include, at a minimum, the following:

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

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

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

(6) In any department review of a grievance involving a disputed health care service, as defined in subdivision (b) of Section 1374.30, that is not eligible for the independent medical review system established pursuant to Article 12 (commencing with Section 1374.30), in which the department finds that the plan has delayed, denied, or modified health care services that are medically necessary, based on the specific medical

circumstances of the enrollee, and those services are a covered benefit under the terms and conditions of the health care service plan contract, the department's written notice shall either: (A) Order the plan to promptly offer and provide those health care services to the enrollee, or (B) Order the plan to promptly reimburse the enrollee for any reasonable costs associated with urgent care or emergency services, or other extraordinary and compelling health care services, when the department finds that the enrollee's decision to secure those services outside of the plan network was reasonable under the circumstances. The department's order shall be binding on the plan.

(7) Distribution of the written notice shall not be deemed a waiver of any exemption or privilege under existing law, including, but not limited to, Section 6254.5 of the Government Code, for any information in connection with and including the written notice, nor shall any person employed or in any way retained by the department be required to testify as to that information or notice.

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

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

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

> ''Under Medicare and Medi-Cal law, Medicare enrollees and Medi-Cal enrollees each have separate avenues of appeal that are not available to other enrollees. Therefore, grievances pending and unresolved may reflect enrollees pursuing their Medicare or Medi-Cal appeal rights.''

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

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

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

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

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

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

(b) The grievance system shall include a requirement for expedited plan review of grievances for cases involving an imminent and serious threat to the health of the patient, including, but not limited to, severe pain, potential loss of life, limb, or major bodily function. When the plan has notice of a case requiring expedited review, the grievance system shall require the plan to immediately inform enrollees and subscribers in writing of their right to notify the department of the grievance. The grievance system shall also require the plan to provide enrollees, subscribers, and the department with a written statement on the disposition or pending status of the grievance no later than three days from receipt of the grievance.

SEC. 4. Section 1368.03 of the Health and Safety Code is amended to read:

1368.03. (a) The department may require enrollees and subscribers to participate in a plan's grievance process for up to 30 days before pursuing a grievance through the department. However, the department may not impose this waiting period for expedited review cases covered by subdivision (b) of Section 1368.01 or in any

other case where the department determines that an earlier review is warranted.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) If Assembly Bill 55 of the 1999–2000 Regular Session is enacted, this section shall remain in effect only until January 1, 2001, and as of that date is repealed, unless a

later enacted statute, that is enacted before January 1, 2001, deletes or extends that date.

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

1368.04. (a) The director shall investigate and take enforcement action against plans regarding grievances reviewed and found by the department to involve noncompliance with the requirements of this chapter, including grievances that have been reviewed pursuant to the independent medical review system established pursuant to Article 12 (commencing with Section 1374.30). Where substantial harm to an enrollee has occurred as a result of plan noncompliance, the director shall, by order, assess administrative penalties subject to appropriate notice of, and the opportunity for, a hearing with regard to the person affected in accordance with Section 1397. The administrative penalties shall not be deemed an exclusive remedy available to the director. These penalties shall be paid to the State Managed Care Fund. The director shall periodically evaluate grievances to determine if any audit, investigative, or enforcement actions should be undertaken by the department.

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

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

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

(c) The administrative penalties available to the director pursuant to this section are not exclusive, and may be sought and employed in any combination with civil, criminal, and other administrative remedies

deemed warranted by the director to enforce this chapter.

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

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

SEC. 8. Section 1370.4 of the Health and Safety Code is amended to read:

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

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

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

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

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

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

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

(3) Either (A) the enrollee's physician, who is under contract with or employed by the plan, has recommended a drug, device, procedure or other therapy that the physician certifies in writing is likely to

be more beneficial to the enrollee than any available standard therapies, or (B) the enrollee, or the enrollee's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's condition, has requested a therapy that, based on two documents from the medical and scientific evidence, as defined in subdivision (d), is likely to be more beneficial for the enrollee than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the plan to pay for the services of a nonparticipating physician provided pursuant to this subdivision, that are not otherwise covered pursuant to the plan contract.

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

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

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

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

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

(2) The department shall contract with one or more impartial, independent entities that are accredited pursuant to subdivision (c). The entity shall arrange for review of the coverage decision of the plan by selecting an independent panel of at least three physicians or other

providers who are experts in the treatment of the enrollee's medical condition and knowledgeable about the recommended therapy. If the entity is an academic medical center accredited in accordance with subdivision (e), the independent panel may include experts affiliated with or employed by the entity. A panel of two experts may be arranged at the plan's request, provided the enrollee consents in writing. The independent entity may arrange for a panel of one expert only if the independent entity certifies in writing that there is only one expert qualified and able to review the recommended therapy. Neither the plan nor the enrollee shall choose or control the choice of the physician or other provider experts.

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

(A) The plan.

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

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

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

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

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

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

(B) ''Material professional affiliation'' means any physician-patient relationship, any partnership or employment relationship, a shareholder or similar ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a material financial affiliation with any expert or any officer

or director of the independent entity. The term ‘‘material professional affiliation’’ does not include affiliations that are limited to staff privileges at a health facility.

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

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

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

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

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

subparagraphs (A) and (C), to the enrollee and the enrollee's physician.

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

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

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

(9) The independent entity shall provide the plan and the enrollee's physician with the experts' analyses and recommendations, a description of the qualifications of each expert, and any other information that it chooses to provide to the plan and the enrollee's physician, including, but not limited to, the names of the expert reviewers. The independent entity shall not be required to disclose the names of the expert reviewers to the plan or the enrollee's physician, except pursuant to a properly made request for discovery. If the independent entity chooses to disclose the names of the experts on the panel

to the plan, the independent entity must also disclose the names of the experts to the enrollee's physician. The enrollee's physician may provide these documents and information to the enrollee.

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

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

(c) The Commissioner of Corporations, in consultation with the Insurance Commissioner, shall, by January 1, 1998, contract with a private, nonprofit accrediting organization to accredit the independent review entities specified in subdivision (b). The accrediting organization shall have the power to grant and revoke accreditation, and shall develop, apply, and enforce accreditation standards, including those required in subdivision (e), that ensure the independence of the independent review entity, the confidentiality of the medical records, and the qualifications and independence of the health care professionals providing the analyses and recommendations requested of them. The accrediting organization shall demonstrate the ability to objectively evaluate the performance of independent entities and shall demonstrate that it has no conflict of interest, including any material professional,

familial, or financial affiliation as defined in paragraph (4) of subdivision (b) with any independent entity or plan, in accrediting entities for the purpose of reviewing medical treatments, treatment recommendations, and coverage decisions by health care service plans.

(d) For the purposes of paragraph (3) of subdivision (a), ‘‘medical and scientific evidence’’ means the following sources:

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

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

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

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

(5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the

purpose of evaluating the medical value of health services.

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

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

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

(2) The independent entity shall submit to the accrediting organization and to the Department of Corporations the following information upon initial application for accreditation and annually thereafter upon any change to any of the following information:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) For purposes of this section, ‘‘seriously debilitating’’ means diseases or conditions that cause major irreversible morbidity.

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

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

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

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

be a covered service, except for the plan's determination that the therapy is experimental or investigational.

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

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

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

(2) If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall be extended by up to three days for a delay in providing the documents required. The timeframes specified in this paragraph shall be in addition to any otherwise applicable timeframes contained in subdivision (c) of Section 1374.33.

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

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

(d) For the purposes of subdivision (b), ‘‘medical and scientific evidence’’ means the following sources:

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

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

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

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

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

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

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

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

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

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

(b) A plan shall not engage in any conduct that has the effect of prolonging the independent review process. The engaging in that conduct or the failure of the plan to promptly implement the decision is a violation of this chapter and, in addition to any other fines, penalties, and other remedies available to the director under this chapter, the plan shall be subject to an administrative penalty of not less than five thousand dollars ($5,000) for each day that the decision is not implemented. Administrative penalties shall be deposited in the State Managed Care Fund.

(c) In any case where an enrollee secured urgent care or emergency services outside of the plan provider network, which services are later found by the independent medical review organization to have been medically necessary pursuant to Section 1374.33, the director shall require the plan to promptly reimburse the enrollee for any reasonable costs associated with those services when the director finds that the enrollee's decision to secure the services outside of the plan provider network prior to completing the plan grievance process or seeking an independent medical review was reasonable under the circumstances and the disputed health care services were a covered benefit under the terms and conditions of the health care service plan contract.

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

(e) Pursuant to Section 1368.04, the director shall perform an annual audit of independent medical review cases for the dual purposes of education and the opportunity to determine if any investigative or enforcement actions should be undertaken by the department, particularly if a plan repeatedly fails to act promptly and reasonably to resolve grievances associated with a delay, denial, or modification of medically necessary health care services when the obligation of the plan to provide those health care services to enrollees or subscribers is reasonably clear.

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

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

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

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

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

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

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

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

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

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

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

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

(3) Either (A) the insured's contracting physician has recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the insured than any available standard therapies, or (B) the insured, or the insured's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the insured's condition,

has requested a therapy that, based on two documents from the medical and scientific evidence, as defined in subdivision (d), is likely to be more beneficial for the insured than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the insurer to pay for the services of a noncontracting physician, provided pursuant to this subdivision, that are not otherwise covered pursuant to the contract.

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

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

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

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

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

(2) The Department of Corporations shall contract with one or more impartial, independent entities that are accredited pursuant to subdivision (c). The entity shall arrange for review of the coverage decision of the insurer by selecting an independent panel of at least three physicians or other providers who are experts in the treatment of the insured's medical condition and

knowledgeable about the recommended therapy. If the entity is an academic medical center accredited in accordance with subdivision (e), the independent panel may include experts affiliated with or employed by the entity. A panel of two experts may be arranged at the insurer's request, provided the insured consents in writing. The independent entity may arrange for a panel of one expert only if the independent entity certifies in writing that there is only one expert qualified and able to review the recommended therapy. Neither the insurer nor the insured shall choose or control the choice of the physician or other provider experts.

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

(A) The insurer.

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

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

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

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

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

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

(B) ''Material professional affiliation'' means any physician-patient relationship, any partnership or employment relationship, a shareholder or similar ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a material financial affiliation with any expert or any officer or director of the independent entity. The term ''material

professional affiliation'' does not include affiliations that are limited to staff privileges at a health facility.

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

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

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

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

(B) A copy of any relevant documents used by the insurer in determining whether the proposed therapy should be covered, and any statement by the insurer explaining the reasons for the insurer's decision not to provide coverage for the proposed therapy. The insurer shall provide, upon request, a copy of the documents required by this paragraph, except for the documents

described in subparagraphs (A) and (C), to the insured and the insured's physician.

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

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

(8) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the insured than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be covered by the insurer, citing the insured's specific medical condition, the relevant documents provided pursuant to paragraph (6), and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.

(9) The independent entity shall provide the insurer and the insured's physician with the expert's analyses and recommendations, a description of the qualifications of each expert, and any other information that it chooses to provide to the insurer and the insured's physician, including, but not limited to, the names of the expert reviewers. The independent entity shall not be required to disclose the names of the expert reviewers to the insurer or to the insured's physician, except pursuant to a properly made request for discovery. If the independent entity chooses to disclose the names of the

experts on the panel to the insurer, the independent entity must also disclose the names of the experts to the insured's physician. The insured's physician may provide these documents and information to the enrollee.

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

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

(c) The Commissioner of Corporations, in consultation with the Insurance Commissioner, shall, by January 1, 1998, contract with a private, nonprofit accrediting organization to accredit the independent review entities specified in subdivision (b). The accrediting organization shall have the power to grant and revoke accreditation, and shall develop, apply, and enforce accreditation standards, including those required in subdivision (e), that ensure the independence of the independent review entity, the confidentiality of the medical records, and the qualifications and independence of the health care professionals providing the analyses and recommendations requested of them. The accrediting organization shall demonstrate the ability to objectively evaluate the performance of independent entities and shall demonstrate that it has no conflict of interest, including any material professional,

familial, or financial affiliation as defined in paragraph (4) of subdivision (b) with any independent entity or disability insurer, in accrediting entities for the purpose of reviewing medical treatments, treatment recommendations, and coverage decisions by disability insurers.

(d) For the purposes of paragraph (3) of subdivision (a), ‘‘medical and scientific evidence’’ means the following sources:

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

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

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

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

(5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the

purpose of evaluating the medical value of health services.

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

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

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

(2) The independent entity shall submit to the accrediting organization and to the Department of Corporations the following information upon initial application for accreditation and annually thereafter upon any change to any of the following information:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(h) Upon the operation of the Department of Managed Care and the appointment of its director, the responsibilities of the Department of Insurance and its commissioner shall be transferred to the Department of Managed Care and its director.

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

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

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

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

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

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

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

(C) For purposes of this section, ‘‘seriously debilitating’’ means diseases or conditions that cause major irreversible morbidity.

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

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

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

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

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

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

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

(1) The insurer shall notify eligible insureds in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

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

(3) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the insured than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be covered by the insurer, citing the insured's specific medical condition, the relevant documents, and the relevant medical and scientific evidence, including, but not limited to, the medical and

scientific evidence as defined in subdivision (d), to support the expert's recommendation.

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

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

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

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

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

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

(5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the

purpose of evaluating the medical value of health services.

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

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

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

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

Approved _____, 1999

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Governor