SENATE BILL No. 254

Introduced by Senator Speier

January 28, 1999

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

LEGISLATIVE COUNSEL'S DIGEST

SB 254, as introduced, Speier. Health insurance.

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

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

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

Existing law requires every health care service plan and disability insurer to establish a reasonable external,

independent review process to examine coverage decisions regarding experimental or investigational therapies for individual enrollees or insureds who have a terminal condition and meet certain specified criteria.

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

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

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

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

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

Under existing law, a willful violation of the provisions governing health care service plans is a crime. By changing the definition of the crime applicable to these plans, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

SECTION 1. The Legislature finds and declares the following:

(a) The California Managed Health Care Improvement Task Force has recommended that California enact an independent system of external review of health plan decisions. A similar recommendation was issued by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Proponents of independent review maintain that this new program will enhance consumer confidence in health plan decisionmaking.

(b) More than 15 states have enacted legislation establishing independent review of health care decisions, and in California, one health plan has voluntarily implemented a process for independent review of a broad range of unresolved patient grievances. In addition, Medicare has a system for independent review of unresolved patient grievances. A great diversity of policies and procedures has been applied to these various state and federal independent review systems.

(c) Recent studies indicate only modest patient participation in state independent review programs, because many consumers are unaware of their right to access independent review. In addition, the studies indicate that many consumers in need of independent

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

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

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

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

SEC. 3. 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 ~~complaints~~ *grievances* to be given to subscribers and enrollees who wish to register written ~~complaints~~ *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 denial, significant delay, termination, or the imposition of other limits on 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 or medical appropriateness.*

(5) Keep in its files all copies of ~~complaints~~ *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 ~~60~~ *30* days, a subscriber or enrollee may submit the grievance ~~or complaint~~ 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 ~~60 days~~ *30 days before submitting a grievance to the department for review.*

(B) A grievance ~~or complaint~~ 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 ~~or complaint~~ *issue*

that does not pertain to compliance with this chapter to the State Department of Health Services, the 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 ~~or complaint~~ 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 ~~or complaint~~ to the department. In addition, following submission of the grievance ~~or complaint~~ 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 complaint~~, 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 is eligible for review under the independent review system established pursuant to Article 12 (commencing with Section 1399.80), the department shall immediately notify the subscriber or enrollee, or agent, of that option and shall, if requested orally or in writing, assist the subscriber or enrollee to apply to participate in the independent medical review system.*

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

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

(5) The department shall send a written notice of the final disposition of the grievance ~~or complaint~~, 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 ~~60~~ *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 ~~or complaint~~. *In any department response to an enrollee grievance not subject to the independent review system established pursuant to Article 12 (commencing with Section 1399.80), the department's written notice shall include, at a minimum, a brief description of the purpose of the department's review, the department's conclusion relating to the grievance along with a summary of the findings supporting the department's conclusion, the reasons why the department concluded that the plan is or is not in compliance with this chapter, and information about corrective and enforcement actions taken by the department.*

(6) 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. ~~On~~

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

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

~~(4)~~

(8) 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 ~~or complaint~~ to the department. The use of mediation services shall not preclude the right to submit a grievance ~~or complaint~~ 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 ~~complaints~~ *grievances* that are pending and unresolved for 30 days or more. On or before January 1, 1997, the plan shall provide a quarterly report to the commissioner of ~~complaints~~ *grievances* pending and unresolved for 30 or more days with separate categories of ~~complaints~~ *grievances* for Medicare enrollees and Medi-Cal enrollees. The plan shall include with the report a brief explanation of the reasons each ~~complaint~~ *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, ~~complaints~~ *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~~ complaints~~ *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 ~~complaints~~ *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~~, complaint,~~ 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 or~~ 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.

SEC. 4. 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 ~~whenever possible~~ and shall require the plan to provide enrollees and subscribers with a written statement on the disposition or pending status of the grievance within ~~30~~ *15* days of the plan's receipt of the grievance.

(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 ~~five~~ *three* days from receipt of the grievance.

SEC. 5. 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 ~~60~~ *30* days before pursuing a ~~complaint~~ *grievance* through the department. However, the department may not impose this waiting period ~~in~~ *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 ~~or complaint~~ *issue that does not pertain to compliance with this chapter* to the State Department of Health Services, the Department of Aging, the federal Health Care Financing Administration, or any other appropriate governmental entity for investigation and resolution.

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

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

as a result of plan noncompliance, the commissioner shall impose penalties. The commissioner shall periodically evaluate ~~complaints~~ *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, levy an administrative penalty, by order, in an amount not to exceed two hundred fifty thousand dollars ($250,000) if the commissioner determines that a health care service plan has knowingly committed, or has performed with ~~such~~ *a* frequency *so* as to indicate 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.

SEC. 7. 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) The enrollee has a terminal condition that, according to the enrollee's physician's current diagnosis, has a high probability of causing death within two years from the date of the request for an independent review; and

(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, or 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); and

(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; and

(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); and

(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; and

(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 plan 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 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 shall 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 shall have the following meanings:

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

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

(C) ''Material financial affiliation'' shall mean 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'' shall not include payment by the plan to the independent entity for the services required by this section, nor shall ''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.

(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 states 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 Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database 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 must be an organization that has as its primary function to provide 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 having as its primary function providing expert reviews and related services and without receiving a majority of its revenues from these services. 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 must 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 July 1, 1998.

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

SEC. 8. 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) The enrollee has a terminal condition that, according to the enrollee's physician's current diagnosis, has a high probability of causing death within two years from the date of the request for an independent review; and

(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, or 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); and

(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; and

(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); and

(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; and

(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 plan 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 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 shall 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 shall have the following meanings:

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

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

(C) ''Material financial affiliation'' shall mean 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'' shall not include payment by the plan to the independent entity for the services required by this section, nor shall ''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.

(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 states 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 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 Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database 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 must be an organization that has as its primary function to provide 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 having as its primary function providing expert reviews and related services and without receiving a majority of its revenues from these services. 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 must 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, 2004.

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

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

Article 12. Appeals Seeking Independent Reviews

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Is frivolous and without merit.

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

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

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

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

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

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

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

(A) The plan.

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

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

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

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

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

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

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

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

(2) The independent review organization shall submit to the accrediting organization and to the department the following information upon initial application for accreditation and, except as otherwise provided, 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 review organization 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 review organization, as well as a statement regarding any past or present 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 of a plan, managed care organization, or provider group.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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 treatment.

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

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

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

(6) For purposes of this section, the following terms shall 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 review organization. ''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 independent review organization or individual to which this subdivision applies. ‘‘Material financial affiliation’’ does not include payment by the plan to the independent review organization 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.

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

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

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

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

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

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

(C) Generally accepted standards of medical practice.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) Pursuant to Section 1368.04, the commissioner shall periodically evaluate independent review cases to determine if any audit, 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 denial, significant delay, termination, or the imposition of other limits on medically necessary or appropriate health care services when the obligation of the plan to provide those health care services to enrollees or subscribers is reasonably clear.

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

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

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

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

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

(A) The health plan grievance process.

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

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

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

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

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

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

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

enrollees, including vulnerable populations served by various health plans.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 10. 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.

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

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