

## Assembly Bill No. 1663

### CHAPTER 979

An act to add Section 1370.4 to the Health and Safety Code, and to add Section 10145.3 to the Insurance Code, relating to health insurance.

[Approved by Governor September 27, 1996. Filed  
with Secretary of State September 27, 1996.]

#### LEGISLATIVE COUNSEL'S DIGEST

AB 1663, Friedman. Health insurance.

Existing law requires every health care service plan and disability insurer that denies coverage for an experimental medical procedure or plan of treatment for a claimant with a terminal illness to provide written notice of the medical and scientific reason for denial, a description of alternative medical treatments, and information about the review process or grievance procedure, as applicable.

This bill would require every health care service plan and disability insurer to establish a reasonable external, independent review process, which would be required on and after July 1, 1998, to examine coverage decisions regarding experimental or investigational therapies for individual enrollees or insureds who meet certain specified criteria. The bill would require the independent review entities to be accredited by a private, nonprofit accrediting organization under contract with the Commissioner of Corporations, in consultation with the Insurance Commissioner. This bill would authorize the accrediting organization to grant and revoke accreditation, and to develop, apply, and enforce accreditation standards, as specified, that ensure the independence of the independent review entity, the confidentiality of medical records, and the qualifications and independence of health care professionals acting as medical experts.

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

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

This bill would state legislative intent.

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

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

SECTION 1. This act shall be known as the Friedman-Knowles Experimental Treatment Act of 1996.

SEC. 2. (a) It is the intent of the Legislature that health care service plans and disability insurers be required to provide an external, independent review by qualified experts when a patient who has a terminal condition is denied coverage for a drug, device, procedure, or other therapy generally considered experimental or investigational. It is further the intent of the Legislature to provide for external, independent review of such a drug, device, procedure, or other therapy to determine if it is medically appropriate for the particular patient.

(b) The Legislature finds and declares that nothing in this act is intended to preclude a health care service plan or disability insurer from covering, at its discretion, treatments that are provided within clinical trials, or from providing the independent review required by this act to enrollees or insureds who do not necessarily meet all of the eligibility requirements of subdivision (a) of Section 1370.4 of the Health and Safety Code or subdivision (a) of Section 10145.3 of the Insurance Code.

SEC. 3. 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, 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 Medica (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.

SEC. 4. Section 10145.3 is added to the Insurance Code, to read:

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



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

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

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

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

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

(6) 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 under investigation.

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

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



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

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

(A) The insurer.

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

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

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

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

(4) For purposes of this section, the following terms 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 insurer to the independent entity for the services required by this section, nor shall "material financial affiliation" include an expert's participation as a contracting provider for the insurer where the



expert is affiliated with an academic medical center or a National Cancer Institute-designated clinical cancer research center.

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

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

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

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

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

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

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



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

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

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

(c) The Commissioner of Corporations, in consultation with the Insurance Commissioner, shall, by January 1, 1998, contract with a private, nonprofit accrediting organization to accredit the independent review entities specified in subdivision (b). The accrediting organization shall have the power to grant and revoke accreditation, and shall develop, apply, and enforce accreditation standards, including those required in subdivision (e), that ensure the independence of the independent review entity, the confidentiality of the medical records, and the qualifications and independence of the health care professionals providing the analyses and recommendations requested of them. The accrediting organization shall demonstrate the ability to objectively evaluate the performance of independent entities and shall demonstrate that it has no conflict of interest, including any material professional, familial, or financial affiliation as defined in paragraph (4) of subdivision (b) with any independent entity or disability insurer, in accrediting entities for the purpose of reviewing medical treatments,



treatment recommendations, and coverage decisions by disability insurers.

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

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

(2) Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National 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 recognize 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.

SEC. 5. 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.

