DEPARTMENT OF
Managed Health Care

State of California
Department of Managed Health Care

September 21, 2010

Jay Angoff
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9993-IFC
P.O. Box 8016
Baltimore, MD 21244-1850

RE: INTERIM FINAL REGULATIONS FOR PHSA § 2719 (INTERNAL CLAIMS, APPEALS AND EXTERNAL REVIEW)
FILE CODE OCIID-9993-IFC

Dear Mr. Angoff:

The California Department of Managed Health Care (DMHC) appreciates the opportunity to comment on the Interim Final Regulations (the Rules) regarding the internal claims, appeals, and external review requirements under the Public Health Services Act (PHSA) section 2719[1], as amended by the Patient Protection and Affordable Coverage Act of 2010 (ACA).

The DMHC is the California agency that licenses and regulates health care service plans (health plans) under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act). There are 108 health plans providing managed health care services to 21 million Californians and operating under this state licensing law.

The DMHC has identified several issues for which comments are provided and additional clarification is requested so that interested parties (health plans, providers, consumers) can better understand their rights and obligations under the federal laws.

I. CALIFORNIA LAW SUFFICIENTLY COMPLIES WITH THE FEDERAL REQUIREMENTS FOR A STATE EXTERNAL REVIEW PROCESS

Under the Knox-Keene Act, health plans are required to provide enrollees with an internal claims process, an internal appeals process, and an external review process. While the Knox-Keene Act's policies for the internal claims and appeals processes differ from the requirements of Section 2719 and the Rules, its external review process appears to substantially comply with the federal requirements.

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[1] 42 U.S.C. section 300gg-19.

Under the Knox-Keene Act, there is an external review process known as the Independent Medical Review (IMR) process that is administered by the DMHC.[2] The DMHC has administered nearly 12,000 IMRs over the past ten years.

The purpose of the Knox-Keene Act's IMR process is to address "disputed health care services." A "disputed health care service" is any health care service eligible for coverage under the health plan's contract that has been denied, modified, or delayed because the plan found the service to not be, in whole or in part, medically necessary. A decision regarding a "disputed health care service" relates to the practice of medicine and is not a coverage decision.

Similar to the Rules, when a health plan denies or modifies a requested service, the Knox-Keene Act requires the health plan to provide the enrollee with a written notice that describes the criteria used and the clinical reasons for the decision.[3] This notice must also inform the enrollee that an IMR process is available to those who are unsatisfied with health plan's decision.[4] If the enrollee has already participated in or exhausted the health plan's internal appeals process, he/she can seek an IMR.[5] The IMR process consists of an independent medical review organization that makes an independent determination of medical necessity based on the enrollee's medical records. The Knox-Keene Act requires the IMR process to be completed within 30 days for non-urgent cases and within three days for urgent cases.[6] The health plans pay for the cost of an IMR, and the result is binding.[7] The same IMR process is also available for claims involving experimental or investigational treatment and services.[8] A copy of the relevant laws and regulations are attached.

In accordance with subsection (c) of Section 2719, we request that the Secretary deem California's external review process to be in compliance with subsection (b) of Section 2719.

II. CALIFORNIA LAWS THAT PROVIDE GREATER CONSUMER PROTECTIONS SHOULD CONTROL

State laws that provide greater consumer protections than the federal law, as is the case in California, should be preserved. The Knox-Keene Act provides greater consumer protections to its citizens by providing faster resolution to claims and faster access to health care services than do the federal provisions.

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[2] Article 5.5 of Chapter 2.2 of Division 2 of the Health and Safety Code (commencing with section 1374.30).
[3] Health and Safety Code section 1367(h)(4).
[4] Health and Safety Code section 1367(h)(4).
[5] Health and Safety Code section 1374.309(i).
[6] Health and Safety Code section 1374.33(c).
[7] Health and Safety Code section 1374.33(f).
[8] Health and Safety Code section 1370.4.

For example, for non-urgent cases, the Knox-Keene Act requires health plans to respond within five business days of receiving a claim (request for authorization), or within five days of receiving additional information requested by the health plan.[9] In contrast, the Rules require health plans to respond within 15 days of receiving a claim. This 15-day period may be extended once, for another 15 days, if the plan administrator determines that it is necessary due to matters beyond its control. Additionally, the Rules provide the claimant up to 45 days after receiving the notice of extension to provide additionally requested information. Requiring the health plans to respond within five days, rather than 15 days, ensures a faster resolution of the claimant's request.

Additionally, the Knox-Keene Act requires health plans to respond to internal appeals (grievances) within 30 days unless the matter is urgent, while the federal law requires a response within 60 days for post-service requests and 30 days for pre-services requests.[10] By requiring health plans to respond to an internal appeal within 30 days, irrespective of whether it pertains to a pre- or post-service request, the claimant will receive a quicker decision on all requests as compared to the federal provisions.

The Knox-Keene Act requirement that health plans provide enrollees with online grievance procedures also provides greater protection to California consumers than do the federal provisions. Health plans are required to provide an online form on their websites that enrollees can use to file an internal grievance with their health plans.[11] Moreover, the online form notifies enrollees that they can file a grievance with the DMHC (the IMR or external review process) if they are not satisfied with the health plan's internal process.[12] The federal law does not provide these consumer protections.

The Knox-Keene Act also requires that for non-urgent cases, an external review response (or IMR response) be completed within 30 days of the Independent Review Organization's receipt of the appeal and supporting documentation.[13] The Rules, however, require a response within 45 days. At the external review stage, the claimant has already participated in or exhausted the health plan's internal appeal process. The Knox-Keene Act provides a faster resolution to the claimant in this final appeal process by requiring a response 15 days earlier than the federal requirement.

Furthermore, the Knox-Keene Act requires health plans to provide language assistance to enrollees with limited English proficiency, including documents and notices in an indicated language, as well as provider translator services.[14] In contrast, the Rules limit language assistance to providing relevant notices in a culturally and linguistically appropriate manner. The scope of the Knox-Keene Act's language assistance services are broader, and provide access to health care information and services to a greater number of enrollees.

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[9] Health and Safety Code Section 1367.01(h).
[10] Health and Safety Code Section 1368.01(a).
[11] Health and Safety Code 1368.015 .
[12] Health and Safety Code 1368.015 (c)(3).
[13] Health and Safety Code Section 1374.33(c).
[14] Health and Safety Code Section 1367.04.

Copies of the relevant laws and regulations are attached. Accordingly, the above California consumer protections should control over the Rules. Please confirm.

III. THE STATE EXTERNAL REVIEW PROCESS SHOULD NOT INCLUDE RESCISSIONS AS AN ADVERSE BENEFIT DETERMINATION

The DMHC has a robust external review process in place that evaluates the appropriateness of a health plan's decision, based on factors such as medical necessity or whether a service is experimental or investigational. Rescission of coverage decisions, in contrast, present issues of fraud and misrepresentation that require a significantly different review process. As such, it would be difficult for states to comply with the federal requirement to evaluate rescission decisions as part their State's external review process. States should be permitted the flexibility to handle rescission decisions in more cost-effective ways. In fact, the DMHC has successfully pursued enforcement actions based on rescission decisions, which have resulted in restoring health care coverage to consumers. Moreover, California has pending legislation that would allow consumers to appeal to their state regulators for resolution of rescission issues.

Notwithstanding the burden that rescissions pose to regulators, the Rules appear to leave open the possibility of including rescissions as an "adverse benefit determination" to be addressed through a state's external review process. The Rules define an "adverse benefit determination" based on the definition provided by 29 CFR 2560.503-1. This rule delineates all plan actions that would be considered to be an "adverse benefit determination" including, but not limited to, any denial, reduction, termination, or failure to provide or make a payment, which would include rescission of coverage. But the Rules also require the state external review process to provide external review of "adverse benefit determinations" that are based on the plan's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, which would not appear to include rescissions.

While the Rules present conflicting descriptions of what is included in the in the definition of an "adverse benefit determination," it is the DMHC's conclusion that the state external review process does not apply to rescission of coverage decisions. Please confirm this conclusion.

IV. CLARIFICATION ON THE PROCESS OF PRESENTING EVIDENCE

The Rules require plans to allow claimants to not only review their claim files, but to present evidence and testimony as part of the internal claims and appeals process. The Rules also require compliance with 29 CFR 2560.503-1(h)(2), which provides the claimant with the opportunity to submit written comments, documents, records, and other information relating to the claim for benefit. Without further guidance, it is not clear what limitations or requirements the claimant must follow in order to properly present evidence or testimony.

For example:

- Is the claimant required to provide his/her evidence at an administrative or civil hearing?
- Is the claimant allowed to informally submit his/her evidence via a telephone or a letter?
- Is the claimant limited in the number of documents or testimonials he/she can present?
- What form, if any, is the claimant required to present his/her evidence?

The costs involved for all interested parties will depend upon the formality of such proceedings. Accordingly, providing additional clarification on these issues will help affected parties to better understand their rights and obligations under the Rules. To the extent possible, procedures should be informal to make it easier for consumers to present evidence and to mitigate any associated costs.

V. CLARIFICATION ON FORM AND MANNER OF NOTICE

The Rules require health plans and health insurance issuers offering group health coverage and individual health coverage to provide participants with relevant notices in a culturally and linguistically appropriate manner. As described by the Rules, it is not clear whether the term "participant" refers to those enrolled in a particular employer group, or to enrollees of the plan as a whole. This clarification is necessary, as it directly impacts the number of enrollees to whom a health plan or issuer will be obligated to provide non-English notices. Without further guidance, fewer enrollees may receive relevant notices in a culturally and linguistically appropriate manner than intended by Section 2719.

VI. CLARIFICATION ON SPECIALIZED PLANS

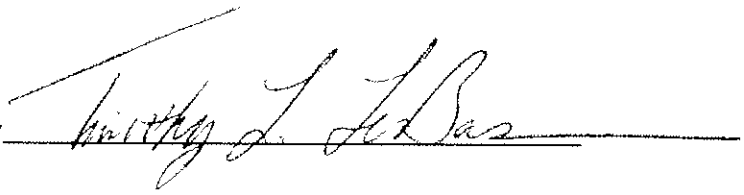
The Rules do not specifically address whether Section 2719 applies to specialized plans, such as vision and dental plans. Further clarification would be helpful regarding the impact of these Rules on such plans.

VII. IMPLEMENTATION TIMELINE

While California's appeals requirements are substantially the same or more stringent in many aspects as discussed above, the Rules also contain certain provisions that require California health plans to significantly modify their current processes. For instance, the Rules require the inclusion of the diagnosis and treatment codes and their meaning on all adverse benefit determinations, while California law only requires health plans to provide an explanation of the reason for a denial, delay or modification of a request for a health care service. Due to the significant changes to current processes, many health plans may not be able to comply with the Rules on the effective date. We encourage you to consider extending the timeline for compliance with the Rules until July 1, 2011. This extended timeframe would permit health plans to transition to the new requirements within a reasonable time period.

Thank you for the opportunity to comment on the proposed Rules. Should you have any questions, please do not hesitate to contact me at (916) 322-2012 or cehnes@dmhc.ca.gov.

Sincerely,

By 

Timothy L. Le Bas
Assistant Deputy Director
Office of Legal Services

LUCINDA A. EHNES, ESQ.
DIRECTOR
CALIFORNIA DEPARTMENT OF MANAGED HEALTH CARE

EM:em

Att.

RELEVANT CALIFORNIA LAW REGARDING GREATER CONSUMER PROTECTION:

KNOX-KEENE ACT PROVISIONS:

§ 1367.01 Written policies and procedures for review and approval, modification, delay or denial of services; Medical director to ensure compliance; Compliance review

(a) A health care service plan and any entity with which it contracts for services that include utilization review or utilization management functions, that prospectively, retrospectively, or concurrently reviews and approves, modifies, delays, or denies, based in whole or in part on medical necessity, requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, or that delegates these functions to medical groups or independent practice associations or to other contracting providers, shall comply with this section.

(b) A health care service plan that is subject to this section shall have written policies and procedures establishing the process by which the plan prospectively, retrospectively, or concurrently reviews and approves, modifies, delays, or denies, based in whole or in part on medical necessity, requests by providers of health care services for plan enrollees. These policies and procedures shall ensure that decisions based on the medical necessity of proposed health care services are consistent with criteria or guidelines that are supported by clinical principles and processes. These criteria and guidelines shall be developed pursuant to Section 1363.5. These policies and procedures, and a description of the process by which the plan reviews and approves, modifies, delays, or denies requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, shall be filed with the director for review and approval, and shall be disclosed by the plan to providers and enrollees upon request, and by the plan to the public upon request.

(c) A health care service plan subject to this section, except a plan that meets the requirements of Section 1351.2, shall employ or designate a medical director who holds an unrestricted license to practice medicine in this state issued pursuant to Section 2050 of the Business and Professions Code or pursuant to the Osteopathic Act, or, if the plan is a specialized health care service plan, a clinical director with California licensure in a clinical area appropriate to the type of care provided by the specialized health care service plan. The medical director or clinical director shall ensure that the process by which the plan reviews and approves, modifies, or denies, based in whole or in part on medical necessity, requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, complies with the requirements of this section.

(d) If health plan personnel, or individuals under contract to the plan to review requests by providers, approve the provider's request, pursuant to subdivision (b), the decision shall be communicated to the provider pursuant to subdivision (h).

(e) No individual, other than a licensed physician or a licensed health care professional who is competent to evaluate the specific clinical issues involved in the health care services requested

by the provider, may deny or modify requests for authorization of health care services for an enrollee for reasons of medical necessity. The decision of the physician or other health care professional shall be communicated to the provider and the enrollee pursuant to subdivision (h).

(f) The criteria or guidelines used by the health care service plan to determine whether to approve, modify, or deny requests by providers prior to, retrospectively, or concurrent with, the provision of health care services to enrollees shall be consistent with clinical principles and processes. These criteria and guidelines shall be developed pursuant to the requirements of Section 1363.5.

(g) If the health care service plan requests medical information from providers in order to determine whether to approve, modify, or deny requests for authorization, the plan shall request only the information reasonably necessary to make the determination.

(h) In determining whether to approve, modify, or deny requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, based in whole or in part on medical necessity, a health care service plan subject to this section shall meet the following requirements:

(1) Decisions to approve, modify, or deny, based on medical necessity, requests by providers prior to, or concurrent with the provision of health care services to enrollees that do not meet the requirements for the 72-hour review required by paragraph (2), shall be made in a timely fashion appropriate for the nature of the enrollee's condition, not to exceed five business days from the plan's receipt of the information reasonably necessary and requested by the plan to make the determination. In cases where the review is retrospective, the decision shall be communicated to the individual who received services, or to the individual's designee, within 30 days of the receipt of information that is reasonably necessary to make this determination, and shall be communicated to the provider in a manner that is consistent with current law. For purposes of this section, retrospective reviews shall be for care rendered on or after January 1, 2000.

(2) When the enrollee's condition is such that the enrollee faces an imminent and serious threat to his or her health, including, but not limited to, the potential loss of life, limb, or other major bodily function, or the normal timeframe for the decision making process, as described in paragraph (1), would be detrimental to the enrollee's life or health or could jeopardize the enrollee's ability to regain maximum function, decisions to approve, modify, or deny requests by providers prior to, or concurrent with, the provision of health care services to enrollees, shall be made in a timely fashion appropriate for the nature of the enrollee's condition, not to exceed 72 hours after the plan's receipt of the information reasonably necessary and requested by the plan to make the determination. Nothing in this section shall be construed to alter the requirements of subdivision (b) of Section 1371.4. Notwithstanding Section 1371.4, the requirements of this division shall be applicable to all health plans and other entities conducting utilization review or utilization management.
(3) Decisions to approve, modify, or deny requests by providers for authorization prior to, or concurrent with, the provision of health care services to enrollees shall be communicated to the requesting provider within 24 hours of the decision. Except for concurrent review decisions

pertaining to care that is underway, which shall be communicated to the enrollee's treating provider within 24 hours, decisions resulting in denial, delay, or modification of all or part of the requested health care service shall be communicated to the enrollee in writing within two business days of the decision. In the case of concurrent review, care shall not be discontinued until the enrollee's treating provider has been notified of the plan's decision and a care plan has been agreed upon by the treating provider that is appropriate for the medical needs of that patient.

(4) Communications regarding decisions to approve requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees shall specify the specific health care service approved. Responses regarding decisions to deny, delay, or modify health care services requested by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees shall be communicated to the enrollee in writing, and to providers initially by telephone or facsimile, except with regard to decisions rendered retrospectively, and then in writing, and shall include a clear and concise explanation of the reasons for the plan's decision, a description of the criteria or guidelines used, and the clinical reasons for the decisions regarding medical necessity. Any written communication to a physician or other health care provider of a denial, delay, or modification of a request shall include the name and telephone number of the health care professional responsible for the denial, delay, or modification. The telephone number provided shall be a direct number or an extension, to allow the physician or health care provider easily to contact the professional responsible for the denial, delay, or modification. Responses shall also include information as to how the enrollee may file a grievance with the plan pursuant to Section 1368, and in the case of Medi-Cal enrollees, shall explain how to request an administrative hearing and aid paid pending under Sections 51014.1 and 51014.2 of Title 22 of the California Code of Regulations.

(5) If the health care service plan cannot make a decision to approve, modify, or deny the request for authorization within the timeframes specified in paragraph (1) or (2) because the plan is not in receipt of all of the information reasonably necessary and requested, or because the plan requires consultation by an expert reviewer, or because the plan has asked that an additional examination or test be performed upon the enrollee, provided the examination or test is reasonable and consistent with good medical practice, the plan shall, immediately upon the expiration of the timeframe specified in paragraph (1) or (2) or as soon as the plan becomes aware that it will not meet the timeframe, whichever occurs first, notify the provider and the enrollee, in writing, that the plan cannot make a decision to approve, modify, or deny the request for authorization within the required timeframe, and specify the information requested but not received, or the expert reviewer to be consulted, or the additional examinations or tests required. The plan shall also notify the provider and enrollee of the anticipated date on which a decision may be rendered. Upon receipt of all information reasonably necessary and requested by the plan, the plan shall approve, modify, or deny the request for authorization within the timeframes specified in paragraph (1) or (2), whichever applies.(6) If the director determines that a health care service plan has failed to meet any of the timeframes in this section, or has failed to meet any other requirement of this section, the director may assess, by order, administrative penalties for each failure. A proceeding for the issuance of an order assessing administrative penalties shall be subject to appropriate notice to, and an opportunity for a hearing with regard to, the

person affected, in accordance with subdivision (a) of Section 1397. The administrative penalties shall not be deemed an exclusive remedy for the director. These penalties shall be paid to the Managed Care Administrative Fines and Penalties Fund and shall be used for the purposes specified in Section 1341.45.

(i) A health care service plan subject to this section shall maintain telephone access for providers to request authorization for health care services.

(j) A health care service plan subject to this section that reviews requests by providers prior to, retrospectively, or concurrent with, the provision of health care services to enrollees shall establish, as part of the quality assurance program required by Section 1370, a process by which the plan's compliance with this section is assessed and evaluated. The process shall include provisions for evaluation of complaints, assessment of trends, implementation of actions to correct identified problems, mechanisms to communicate actions and results to the appropriate health plan employees and contracting providers, and provisions for evaluation of any corrective action plan and measurements of performance.

(k) The director shall review a health care service plan's compliance with this section as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, and shall include a discussion of compliance with this section as part of its report issued pursuant to that section.

(l) This section shall not apply to decisions made for the care or treatment of the sick who depend upon prayer or spiritual means for healing in the practice of religion as set forth in subdivision (a) of Section 1270.

(m) Nothing in this section shall cause a health care service plan to be defined as a health care provider for purposes of any provision of law, including, but not limited to, Section 6146 of the Business and Professions Code, Sections 3333.1 and 3333.2 of the Civil Code, and Sections 340.5, 364, 425.13, 667.7, and 1295 of the Code of Civil Procedure.

§ 1368.01. Time period in which to resolve grievances; Expedited review for cases involving serious threat to patient's health

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

(b) The grievance system shall include a requirement for expedited plan review of grievances for cases involving an imminent and serious threat to the health of the patient, including, but not limited to, severe pain, potential loss of life, limb, or major bodily function. When the plan has notice of a case requiring expedited review, the grievance system shall require the plan to immediately inform enrollees and subscribers in writing of their right to notify the department of the grievance. The grievance system shall also require the plan to provide enrollees, subscribers, and the department with a written statement on the disposition or pending status of the grievance

no later than three days from receipt of the grievance. Paragraph (4) of subdivision (a) of Section 1368 shall not apply to grievances handled pursuant to this section.

§ 1368.015. Online grievance procedure

(a) Effective July 1, 2003, every plan with an Internet Web site shall provide an online form through its Internet Web site that subscribers or enrollees can use to file with the plan a grievance, as described in Section 1368, online.

(b) The Internet Web site shall have an easily accessible online grievance submission procedure that shall be accessible through a hyperlink on the Internet Web site's home page or member services portal clearly identified as "GRIEVANCE FORM." All information submitted through this process shall be processed through a secure server.

(c) The online grievance submission process shall be approved by the Department of Managed Health Care and shall meet the following requirements:

(1) It shall utilize an online grievance form in HTML format that allows the user to enter required information directly into the form.

(2) It shall allow the subscriber or enrollee to preview the grievance that will be submitted, including the opportunity to edit the form prior to submittal.

(3) It shall include a current hyperlink to the California Department of Managed Health Care Internet Web site, and shall include a statement in a legible font that is clearly distinguishable from other content on the page and is in a legible size and type, containing the following language:

"The California Department of Managed Health Care is responsible for regulating health care service plans. If you have a grievance against your health plan, you should first telephone your health plan at (insert health plan's telephone number) and use your health plan' s grievance process before contacting the department. Utilizing this grievance procedure does not prohibit any potential legal rights or remedies that may be available to you. If you need help with a grievance involving an emergency, a grievance that has not been satisfactorily resolved by your health plan, or a grievance that has remained unresolved for more than 30 days, you may call the department for assistance. You may also be eligible for an Independent Medical Review (IMR). If you are eligible for IMR, the IMR process will provide an impartial review of medical decisions made by a health plan related to the medical necessity of a proposed service or treatment, coverage decisions for treatments that are experimental or investigational in nature and payment disputes for emergency or urgent medical services. The department also has a toll-free telephone number (1-888-HMO-2219) and a TDD line (1-877-688-9891) for the hearing and speech impaired. The department' s Internet Web site http://www.hmohelp.ca.gov has complaint forms, IMR application forms and instructions online."

The plan shall update the URL, hyperlink, and telephone numbers in this statement as necessary.

(d) A plan that utilizes a hardware system that does not have the minimum system requirements to support the software necessary to meet the requirements of this section is exempt from these requirements until January 1, 2006.

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

(1) "Homepage" means the first page or welcome page of an Internet Web site that serves as a starting point for navigation of the Internet Web site.

(2) "HTML" means Hypertext Markup Language, the authoring language used to create documents on the World Wide Web, which defines the structure and layout of a Web document.

(3) "Hyperlink" means a special HTML code that allows text or graphics to serve as a link that, when clicked on, takes a user to another place in the same document, to another document, or to another Internet Web site or Web page.

(4) "Member services portal" means the first page or welcome page of an Internet Web site that can be reached directly by the Internet Web site's homepage and that serves as a starting point for a navigation of member services available on the Internet Web site.

(5) "Secure server" means an Internet connection to an Internet Web site that encrypts and decrypts transmissions, protecting them against third-party tampering and allowing for the secure transfer of data.

(6) "URL" or "Uniform Resource Locator" means the address of an Internet Web site or the location of a resource on the World Wide Web that allows a browser to locate and retrieve the Internet Web site or the resource.

(7) "Internet Web site" means a site or location on the World Wide Web.

(f) (1) Every health care service plan, except a plan that primarily serves Medi-Cal or Healthy Families Program enrollees, shall maintain an Internet Web site. For a health care service plan that provides coverage for professional mental health services, the Internet Web site shall include, but not be limited to, providing information to subscribers, enrollees, and providers that will assist subscribers and enrollees in accessing mental health services as well as the information described in Section 1368.016.

(2) The provision in paragraph (1) that requires compliance with Section 1368.016 shall not apply to a health care service plan that contracts with a specialized health care service plan, insurer, or other entity to cover professional mental health services for its enrollees, provided that the health care service plan provides a link on its Internet Web site to an Internet Web site operated by the specialized health care service plan, insurer, or other entity with which it contracts, and that plan, insurer, or other entity complies with Section 1368.016.

§ 1367.04. Language assistance in obtaining health care services; Adoption of regulations and standards; Considerations; Reports; Public input; Contracts

(a) Not later than January 1, 2006, the department shall develop and adopt regulations establishing standards and requirements to provide health care service plan enrollees with appropriate access to language assistance in obtaining health care services.

(b) In developing the regulations, the department shall require every health care service plan and specialized health care service plan to assess the linguistic needs of the enrollee population, excluding Medi-Cal enrollees, and to provide for translation and interpretation for medical services, as indicated. A health care service plan that participates in the Healthy Families Program may assess the Healthy Families Program enrollee population separately from the remainder of its enrollee population for purposes of subparagraph (A) of paragraph (1). A health care service plan that chooses to separate its Healthy Families Program enrollment from the remainder of its enrollee population shall treat the Healthy Families Program population separately for purposes of determining whether subparagraph (A) of paragraph (1) is applicable, and shall also treat the Healthy Families Program population separately for purposes of applying the percentage and numerical thresholds in subparagraph (A) of paragraph (1). The regulations shall include the following:

(1) Requirements for the translation of vital documents that include the following:

(A) A requirement that all vital documents, as defined pursuant to subparagraph (B), be translated into an indicated language, as follows:

(i) A health care service plan with an enrollment of 1,000,000 or more shall translate vital documents into the top two languages other than English as determined by the needs assessment as required by this subdivision and any additional languages when 0.75 percent or 15,000 of the enrollee population, whichever number is less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(ii) A health care service plan with an enrollment of 300,000 or more but less than 1,000,000 shall translate vital documents into the top one language other than English as determined by the needs assessment as required by this subdivision and any additional languages when 1 percent or 6,000 of the enrollee population, whichever number is
less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(iii) A health care service plan with an enrollment of less than 300,000 shall translate vital documents into a language other than English when 3,000 or more or 5 percent of the enrollee population, whichever number is less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(B) Specification of vital documents produced by the plan that are required to be translated. The specification of vital documents shall not exceed that of the Department of Health and Human Services(HHS) Office of Civil Rights (OCR) Policy Guidance (65 Federal Register 52762 (August 30, 2000)), but shall include all of the following:

(i) Applications.

(ii) Consent forms.

(iii) Letters containing important information regarding eligibility and participation criteria.

(iv) Notices pertaining to the denial, reduction, modification, or termination of services and benefits, and the right to file a grievance or appeal.

(v) Notices advising limited-English-proficient persons of the availability of free language assistance and other outreach materials that are provided to enrollees.

(vi) Translated documents shall not include a health care service plan's explanation of benefits or similar claim processing information that is sent to enrollees, unless the document requires a response by the enrollee.

(C)(i) For those documents described in subparagraph (B) that are not standardized but contain enrollee specific information, health care service plans shall not be required to translate the documents into the threshold languages identified by the needs assessment as required by this subdivision, but rather shall include with the documents a written notice of the availability of interpretation services in the threshold languages identified by the needs assessment as required by this subdivision.

(ii) Upon request, the enrollee shall receive a written translation of the documents described in clause (i). The health care service plan shall have up to, but not to exceed, 21 days to comply with the enrollee's request for a written translation. If an enrollee requests a translated document, all timeframes and deadline requirements related to the document that apply to the health care service plan and enrollees under the provisions of this chapter and under any regulations adopted pursuant to this chapter shall begin to run upon the health care service plan's issuance of the translated document.

(iii) For grievances that require expedited plan review and response in accordance with subdivision (b) of Section 1368.01, the health care service plan may satisfy this requirement by providing notice of the availability and access to oral interpretation services.

(D) A requirement that health care service plans advise limited-English-proficient enrollees of the availability of interpreter services.

(2) Standards to ensure the quality and accuracy of the written translations and that a translated document meets the same standards required for the English language version of the document. The English language documents shall determine the rights and obligations of the parties, and the translated documents shall be admissible in evidence only if there is a dispute regarding a substantial difference in the material terms and conditions of the English language document and the translated document.

(3) Requirements for surveying the language preferences and needs assessments of health care service plan enrollees within one year of the effective date of the regulations that permit health care service plans to utilize various survey methods, including, but not limited to, the use of existing enrollment and renewal processes, subscriber newsletters, or other mailings. Health care service plans shall update the needs assessment, demographic profile, and language translation requirements every three years.

(4) Requirements for individual enrollee access to interpretation services.

(5) Standards to ensure the quality and timeliness of oral interpretation services provided by health care service plans.

(c) In developing the regulations, standards, and requirements, the department shall consider the following:

(1) Publications and standards issued by federal agencies, such as the Culturally and Linguistically Appropriate Services (CLAS) in Health Care issued by the United States Department of Health and Human Services Office of Minority Health in December 2000, and the Department of Health and Human Services (HHS) Office of Civil Rights (OCR) Policy Guidance (65 Federal Register 52762 (August 30, 2000)).

(2) Other cultural and linguistic requirements under state programs, such as Medi-Cal Managed Care Policy Letters, cultural and linguistic requirements imposed by the State Department of Health Services on health care service plans that contract to provide Medi-Cal managed care services, and cultural and linguistic requirements imposed by the Managed Risk Medical Insurance Board on health care service plans that contract to provide services in the Healthy Families Program.

(3) Standards adopted by other states pertaining to language assistance requirements for health care service plans.

(4) Standards established by California or nationally recognized accrediting, certifying, or licensing organizations and medical and health care interpreter professional associations regarding interpretation services.

(5) Publications, guidelines, reports, and recommendations issued by state agencies or advisory committees, such as the report card to the public on the comparative performance of plans and reports on cultural and linguistic services issued by the Office of Patient Advocate and the report

to the Legislature from the Task Force on Culturally and Linguistically Competent Physicians and Dentists established by Section 852 of the Business and Professions Code.

(6) Examples of best practices relating to language assistance services by health care providers and health care service plans, including existing practices.

(7) Information gathered from complaints to the HMO Helpline and consumer assistance centers regarding language assistance services.

(8) The cost of compliance and the availability of translation and interpretation services and professionals.

(9) Flexibility to accommodate variations in plan networks and method of service delivery. The department shall allow for health care service plan flexibility in determining compliance with the standards for oral and written interpretation services.

(d) The department shall work to ensure that the biennial reports required by this section, and the data collected for those reports, are consistent with reports required by government-sponsored programs and do not require duplicative or conflicting data collection or reporting.

(e) The department shall seek public input from a wide range of interested parties through advisory bodies established by the director.

(f) A contract between a health care service plan and a health care provider shall require compliance with the standards developed under this section. In furtherance of this section, the contract shall require providers to cooperate with the plan by providing any information necessary to assess compliance.

(g) The department shall report biennially to the Legislature and advisory bodies established by the director regarding plan compliance with the standards, including results of compliance audits made in conjunction with other audits and reviews. The reported information shall also be included in the publication required under subparagraph (B) of paragraph (3) of subdivision (c) of Section 1368.02. The department shall also utilize the reported information to make recommendations for changes that further enhance standards pursuant to this section. The department may also delay or otherwise phase-in implementation of standards and requirements in recognition of costs and availability of translation and interpretation services and professionals.

(h)(1) Except for contracts with the State Department of Health Services Medi-Cal program, the standards developed under this section shall be considered the minimum required for compliance.

(2) The regulations shall provide that a health plan is in compliance if the plan is required to meet the same or similar standards by the Medi-Cal program, either by contract or state law, if the standards provide as much access to cultural and linguistic services as the standards

established by this section for an equal or higher number of enrollees and therefore meet or exceed the standards of the regulations established pursuant to this section, and the department determines that the health care service plan is in compliance with the standards required by the Medi-Cal program. To meet this requirement, the department shall not be required to perform individual audits. The department shall, to the extent feasible, rely on audits, reports, or other oversight and enforcement methods used by the State Department of Health Services.

(3) The determination pursuant to paragraph (2) shall only apply to the enrollees covered by the Medi-Cal program standards. A health care service plan subject to paragraph (2) shall comply with the standards established by this section with regard to enrollees not covered by the Medi-Cal program.

(i) Nothing in this section shall prohibit a government purchaser from including in their contracts additional translation or interpretation requirements, to meet linguistic or cultural needs, beyond those set forth pursuant to this section.

CALIFORNIA CODE OF REGULATION PROVISIONS:

§ 1300.68. Grievance System

Every health care service plan shall establish a grievance system pursuant to the requirements of Section 1368 of the Act.

(a) The grievance system shall be established in writing and provide for procedures that will receive, review and resolve grievances within 30 calendar days of receipt by the plan, or any provider or entity with delegated authority to administer and resolve the plan's grievance system. The following definitions shall apply with respect to the regulations relating to grievance systems:

(1) "Grievance" means a written or oral expression of dissatisfaction regarding the plan and/or provider, including quality of care concerns, and shall include a complaint, dispute, request for reconsideration or appeal made by an enrollee or the enrollee's representative. Where the plan is unable to distinguish between a grievance and an inquiry, it shall be considered a grievance.

(2) "Complaint" is the same as "grievance."

(3) "Complainant" is the same as "grievant," and means the person who filed the grievance including the enrollee, a representative designated by the enrollee, or other individual with authority to act on behalf of the enrollee.

(4) "Resolved" means that the grievance has reached a final conclusion with respect to the enrollee's submitted grievance, and there are no pending enrollee appeals within the plan's grievance system, including entities with delegated authority.

(A) If the plan has multiple internal levels of grievance resolution or appeal, all levels must be completed within 30 calendar days of the plan's receipt of the grievance.

(B) Grievances that are not resolved within 30 calendar days, or grievances referred to the Department's complaint or independent medical review system, shall be reported as "pending" grievances pursuant to subsection (f) below. Grievances referred to external review processes, such as reviews of Medicare Managed Care determinations pursuant to 42 C.F.R. Part 422, or the Medi-Cal Fair Hearing process, shall also be reported pursuant to Subsection (f) until the review and any required action by the plan resulting from the review is completed.

(b) The plan's grievance system shall include the following:

(1) An officer of the plan shall be designated as having primary responsibility for the plan's grievance system whether administered directly by the plan or delegated to another entity. The officer shall continuously review the operation of the grievance system to identify any emergent patterns of grievances. The system shall include the reporting procedures in order to improve plan policies and procedures.

(2) Each plan's obligation for notifying subscribers and enrollees about the plan's grievance system shall include information on the plan's procedures for filing and resolving grievances, and the telephone number and address for presenting a grievance. The notice shall also include information regarding the Department's review process, the independent medical review system, and the Department's toll-free telephone number and website address.

(3) The grievance system shall address the linguistic and cultural needs of its enrollee population as well as the needs of enrollees with disabilities. The system shall ensure all enrollees have access to and can fully participate in the grievance system by providing assistance for those with limited English proficiency or with a visual or other communicative impairment. Such assistance shall include, but is not limited to, translations of grievance procedures, forms, and plan responses to grievances, as well as access to interpreters, telephone relay systems and other devices that aid disabled individuals to communicate. Plans shall develop and file with the Department a policy describing how they ensure that their grievance system complies with this subsection within 90 days of the effective date of this regulation.

(4) The plan shall maintain a toll-free number, or a local telephone number in each service area, for the filing of grievances.

(5) A written record shall be made for each grievance received by the plan, including the date received, the plan representative recording the grievance, a summary or other document describing the grievance, and its disposition. The written record of grievances shall be reviewed periodically by the governing body of the plan, the public policy body created pursuant to Section 1300.69, and by an officer of the plan or his designee. This review shall be thoroughly documented.

(6) The plan grievance system shall ensure that assistance in filing grievances shall be provided at each location where grievances may be submitted. A "patient advocate" or ombudsperson may be used.

(7) Grievance forms and a description of the grievance procedure shall be readily available at each facility of the plan, on the plan's website, and from each contracting provider's office or facility. Grievance forms shall be provided promptly upon request.

(8) The plan shall assure that there is no discrimination against an enrollee or subscriber (including cancellation of the contract) on the grounds that the complainant filed a grievance.

(9) The grievance system shall allow enrollees to file grievances for at least 180 calendar days following any incident or action that is the subject of the enrollee's dissatisfaction.

(c) Through periodic medical surveys under Section 1380 of the Act, the Department shall periodically review the plan's grievance system, including the records of grievances received by the plan, and assess the effectiveness of the plan policies and actions taken in response to grievances.

(d) The plan shall respond to grievances as follows:

(1) A grievance system shall provide for a written acknowledgment within five (5) calendar days of receipt, except as noted in subsection (d)(8). The acknowledgment will advise the complainant that the grievance has been received, the date of receipt, and provide the name of the plan representative, telephone number and address of the plan representative who may be contacted about the grievance.

(2) The grievance system shall provide for a prompt review of grievances by the management or supervisory staff responsible for the services or operations which are the subject of the grievance.

(3) The plan's resolution, containing a written response to the grievance shall be sent to the complainant within thirty (30) calendar days of receipt, except as noted in Subsection (d)(8). The written response shall contain a clear and concise explanation of the plan's decision. Nothing in this regulation requires a plan to disclose information to the grievant that is otherwise confidential or privileged by law.

(4) For grievances involving delay, modification or denial of services based on a determination in whole or in part that the service is not medically necessary, the plan shall include in its written response, the reasons for its determination. The response shall clearly state the criteria, clinical guidelines or medical policies used in reaching the determination. The plan's response shall also advise the enrollee that the determination may be considered by the Department's independent medical review system. The response shall include an application for independent medical review and instructions, including the Department's toll-free telephone number for further

information and an envelope addressed to the Department of Managed Health Care, HMO Help Center, 980 Ninth Street, 5th Floor, Sacramento, CA 95814.

(5) Plan responses to grievances involving a determination that the requested service is not a covered benefit shall specify the provision in the contract, evidence of coverage or member handbook that excludes the service. The response shall either identify the document and page where the provision is found, direct the grievant to the applicable section of the contract containing the provision, or provide a copy of the provision and explain in clear concise language how the exclusion applied to the specific health care service or benefit requested by the enrollee. In addition to the notice set forth at Section 1368.02(b) of the Act, the response shall also include a notice that if the enrollee believes the decision was denied on the grounds that it was not medically necessary, the Department should be contacted to determine whether the decision is eligible for an independent medical review.

(6) Copies of grievances and responses shall be maintained by the Plan for five years, and shall include a copy of all medical records, documents, evidence of coverage and other relevant information upon which the plan relied in reaching its decision.

(7) The Department's telephone number, the California Relay Service's telephone numbers, the plan's telephone number and the Department's Internet address shall be displayed in all of the plan's acknowledgments and responses to grievances in 12-point boldface type with the statement contained in subsection (b) of Section 1368.02 of the Act.

(8) Grievances received over the telephone that are not coverage disputes, disputed health care services involving medical necessity or experimental or investigational treatment, and that are resolved by the close of the next business day, are exempt from the requirement to send a written acknowledgment and response. The plan shall maintain a log of all such grievances containing the date of the call, the name of the complainant, member identification number, nature of the grievance, nature of resolution, and the plan representative's name who took the call and resolved the grievance. The information contained in this log shall be periodically reviewed by the plan as set forth in Subsection (b).

(e) The plan's grievance system shall track and monitor grievances received by the plan, or any entity with delegated authority to receive or respond to grievances. The system shall:

(1) Monitor the number of grievances received and resolved; whether the grievance was resolved in favor of the enrollee or plan; and the number of grievances pending over 30 calendar days. The system shall track grievances under categories of Commercial, Medicare and Medi-Cal/other contracts. The system shall indicate whether an enrollee grievance is pending at: (1) the plan's internal grievance system; (2) the Department's consumer complaint process; (3) the Department's Independent Medical Review system; (4) an action filed or before a trial or appellate court; or (5) other dispute resolution process. Additionally, the system shall indicate whether an enrollee grievance has been submitted to: (1) the Medicare review and appeal system; (2) the Medi-Cal fair hearing process; or (3) arbitration.

(2) The system shall be able to indicate the total number of grievances received, pending and resolved in favor of the enrollee at all levels of grievance review and to describe the issue or issues raised in grievances as (1) coverage disputes, (2) disputes involving medical necessity, (3) complaints about the quality of care and (4) complaints about access to care (including complaints about the waiting time for appointments), and (5) complaints about the quality of service, and (6) other issues.

(f) Quarterly Reports

(1) All plans shall submit a quarterly report to the Department describing grievances that were or are pending and unresolved for 30 days or more. The report shall be prepared for the quarters ending March 31st, June 30th, September 30th and December 31st of each calendar year. The report shall also contain the number of grievances referred to external review processes, such as reconsiderations of Medicare Managed Care determinations pursuant to 42 C.F.R. Part 422, the Medi-Cal fair hearing process, the Department's complaint or Independent Medical Review system, or other external dispute resolution systems, known to the plan as of the last day of each quarter.

(2) The quarterly report shall include:

(A) The licensee's name, quarter and date of the report;
(B) The total number of grievances filed by enrollees that were or are pending and unresolved for more than 30 calendar days at any time during the quarter under the categories of Commercial, Medicare, and Medi-Cal/other products offered by the plan;

(C) A brief explanation of why the grievance was not resolved in 30 days, and indicate whether the grievance was or is pending at: (1) the plan's internal grievance system; (2) the Department's consumer complaint process; (3) the Department's Independent Medical Review system; (4) court; or (5) other dispute resolution processes. Alternatively, the plan shall indicate whether the grievance was or is submitted to: (1) the Medicare review and appeal system; (2) the Medi-Cal fair hearing process; or (3) arbitration.

(D) The nature of the unresolved grievances as (1) coverage disputes; (2) disputes involving medical necessity; (3) complaints about the quality of care; (4) complaints about access to care (including complaints about the waiting time for appointments); (5) complaints about the quality of service; and (6) other issues. All issues reasonably described in the grievance shall be separately categorized.

(E) The quarterly report shall not contain personal or confidential information with respect to any enrollee.

(3) The quarterly report shall be verified by an officer authorized to act on behalf of the plan. The report shall be submitted in writing or through electronic filing to the Department's Sacramento Office to the attention of the Filing Clerk no later than 30 days after each quarter. The quarterly report shall not be filed as an amendment to the plan application.

(4) The quarterly report shall be filed in the format specified in subsection (i).

(g) An enrollee may submit a grievance to the Department. The Department shall notify the plan, and within five (5) calendar days after notification, the plan shall provide the following information to the Department:

(1) A written response to the issues raised by the grievance.

(2) A copy of the plan's original response sent to the enrollee regarding the grievance.

(3) A complete and legible copy of all medical records related to the grievance. The plan shall inform the Department if medical records were not used by the plan in resolving the grievance.

(4) A copy of the cover page and all relevant pages of the enrollee's Evidence of Coverage (EOC), with the specific applicable sections underlined. If the plan relied solely on the EOC, the plan shall notify the Department of that fact.

(5) All other information used by the plan or relevant to the resolution of the grievance.

(6) The Department may request additional information or medical records from the plan. Within five (5) calendar days of receipt of the Department's request, the plan shall forward information and records that are maintained by the plan or any contracting provider. If requested information cannot be timely forwarded to the Department, the plan's response will describe the actions being taken to obtain the information or records and when receipt is expected.

(h) Nothing in this section shall preclude an enrollee from seeking assistance directly from the Department in cases involving an imminent or serious threat to the health of the enrollee or where the Department determines an earlier review is warranted. In such cases, the Department may require the plan and contracting providers to expedite the delivery of information.

The Department may consider the failure of a plan to timely provide the requested information as evidence in favor of the enrollee's position in the Department's review of grievances submitted under subsection (b) of Section 1368 of the Act.

STATE OF CALIFORNIA
Department of Managed Health Care

QUARTERLY REPORT OF
PENDING AND UNRESOLVED GRIEVANCES
PURSUANT TO HEALTH AND SAFETY CODE SECTION 1368(c)

Name of Licensed Health Plan (as appearing on license):

_____
Full Name

DMHC Plan File Number: _____ - _____

Report for the _____ Quarter of 200 _____
1st, 2nd, 3rd, or 4th — Year

3. Categories of Complaints Included in this Report: (Include total plan enrollment for each category.)

Category		Enrollment
_____	Commercial	_____
_____	Medicare	_____
_____	Medi-Cal	_____
_____	Healthy Families	_____

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

Total Number of Grievances Unresolved Within 30 Days During the Quarter
Note: These include all grievances received by the plan or any entity to which the plan has delegated grievance resolution.

	Total	Commercial	Medicare	Medi-Cal
A. Total number of grievances pending or submitted over 30 days at the beginning of the quarter				
B. Total number of additional grievances which exceeded the 30 days timeframe for resolution during this quarter				

C. Total number of grievances that were unresolved within 30 days at any time during quarter (A + B)				
D. Total number of grievances pending or submitted over 30 days at the end of the quarter				

Commercial Members

Number of Commercial Member Grievances Unresolved Within 30 Days During the Quarter by Type of Grievance

Reason Why Pending Over 30 Days	Total All Grievance Types	Coverage Disputes	Disputes Involving Medical Necessity	Quality of Care	Access to Care (including appointments)	Quality of Service
1. Pending in Plan's Internal Grievance System						
2. Pending in Department's consumer complaint process						
3. Pending in Department's Independent Medical Review system						
4. Submitted to Arbitration						
5. Pending in Court						
6. Pending, other dispute resolution						
Total						

Medicare Members

Note: Complete if Medicare+Choice products provided by Plan

Number of Medicare Member Grievances Unresolved Within 30 Days During the Quarter by Type of Grievance

Reason Why Pending Over 30 Days	Total All Grievance Types	Coverage Disputes	Disputes Involving Medical Necessity	Quality of Care	Access to Care (including appointments)	Quality of Service
1. Pending in Plan's Internal Grievance System						
2. Submitted to Medicare Appeals System						
3. Pending in Department's consumer complaint process						
4. Pending in Department's Independent Medical Review system						
5. Submitted to Arbitration						
6. Pending in Court						
7. Pending, other dispute resolution						
Total						

Medi-Cal Members

Note: Complete if Medi-Cal Managed Care products offered by Plan

Number of Medi-Cal Member Grievances Unresolved Within 30 Days During the Quarter by Type of Grievance

Reason Why Pending Over 30 Days	Total All Grievance Types	Coverage Disputes	Disputes Involving Medical Necessity	Quality of Care	Access to Care (including appointments)	Quality of Service
1. Pending in Plan's Internal Grievance System						
2. Submitted to Medi-Cal fair hearing process						
3. Pending in Department's consumer complaint process						

4. Pending in Department's Independent Medical Review system						
5. Submitted to Arbitration						
6. Pending in Court						
7. Pending, other dispute resolution						
Total						

I, the undersigned, have read and signed this report and know the contents thereof, and verify that, to the best of my knowledge and belief, the information included in this report is true.

Signed By: _____
Print or Type Full Name – First Middle and Last Names

Title: _____

Phone Number: ( ) _____
Area Code

§ 1300.68.01. Expedited Review of Grievances

(a) Every plan shall include in its grievance system, procedures for the expedited review of grievances involving an imminent and serious threat to the health of the enrollee, including, but not limited to, severe pain, potential loss of life, limb or major bodily function ("urgent grievances"). At a minimum, plan procedures for urgent grievances shall include:

(1) Immediate notification to the complainant of the right to contact the Department regarding the grievance. The plan shall expedite its review of the grievance when the complainant, an authorized representative, or treating physician provides notice to the plan. Notice need not be in writing, but may be accomplished by a documented telephone call.

(2) A written statement to the Department and the complainant on the disposition or pending status of the urgent grievance within three (3) calendar days of receipt of the grievance by the Plan.

(3) Consideration by the plan of the enrollee's medical condition when determining the response time.

(4) No requirement that the enrollee participate in the plan's grievance process prior to applying to the Department for review of the urgent grievance.

(b) Each plan's grievance system shall allow for the Department to contact the plan regarding urgent grievances 24 hours a day, 7 days a week. During normal work hours, the plan shall respond to the Department within 30 minutes after initial contact from the Department. During non-work hours, the plan shall respond to the Department within 1 hour after initial contact from the Department.

(1) The system established by the plan shall provide for the availability of a plan representative with authority on the plan's behalf to resolve urgent grievances and authorize the provision of health care services covered under the enrollee's plan contract in a medically appropriate and timely manner. Such authority shall include making financial decisions for expenditure of funds on behalf of the plan without first having to obtain approval from supervisors or other superiors within the plan. Nothing in this subsection shall restrict the plan representative from consulting with other plan staff on urgent grievances.

(2) Plans shall provide the Department with the following information concerning urgent grievances:

(A) A description of the system established by the plan to resolve urgent grievances. The description shall include the system's provisions for scheduling qualified plan representatives, including back-up plan representatives as necessary, to be available twenty-four (24) hours a day, seven days a week to respond to Department contacts regarding urgent grievances. Provisions for scheduling shall include the names and titles of those plan representatives who will be available under the system, their telephone numbers, and, as applicable, pager numbers, answer service numbers, voice-mail numbers, e-mail addresses, or other means for contact.

(B) A description of how the Department may access the grievance system established by the plan.

(3) If the plan revises the system established pursuant to subsection (b), the plan shall notify the Department at least thirty (30) days in advance of implementing the revisions.

(c) The plan shall notify the Department before changing or modifying any benefit or services that relates to the urgent grievance submitted to the Department pursuant to subsection (b)(1)(A) of Section 1368 of the Act if the enrollee or the enrollee's representative objects to the change or modification.

§ 1300.67.04. Language Assistance Programs

(a) Application.

(1) Every health care service plan, including specialized health care service plans (plans), shall comply with the requirements of this section. The requirements of this section shall not apply to plan contracts for the provision of services to Medi-Cal enrollees or to contracts between plans and the federal government for the provision of services to Medicare enrollees.

(2) If a plan has both Medi-Cal and non-Medi-Cal lines of business, then the plan will be in compliance with the requirements of this section as to its non-Medi-Cal lines of business if:

(A) The Medi-Cal standards for providing language assistance services, including standards for timeliness and proficiency of interpreters, are equivalent to or exceed the standards set forth in Section 1367.04 of the Act and this section;

(B) The plan applies the Medi-Cal standards for language assistance programs to the plan's non-Medi-Cal lines of business; and

(C) The Department of Managed Health Care (Department) determines, as described in Section 1367.04(h)(3) of the Act, that the plan is in compliance with the Medi-Cal standards.

(3) A plan that seeks the Department's determination of compliance as provided in subsection (a)(2) shall request such determination as part of its filing pursuant to subsection (e)(2) and provide documentation sufficient to support and verify the request to the Department's satisfaction. The Department's determination pursuant to subsection (a)(2) shall apply only to the enrollees in a plan's non-Medi-Cal lines of business to which the plan actually applies the plan's Medi-Cal program standards.

(b) Definitions.

(1) Demographic profile means, at a minimum, identification of an enrollee's preferred spoken and written language, race and ethnicity.

(2) Interpretation: the act of listening to something spoken or reading something written in one language (source language) and orally expressing it accurately and with appropriate cultural relevance into another language (target language).

(3) Limited English Proficient or LEP Enrollee: an enrollee who has an inability or a limited ability to speak, read, write, or understand the English language at a level that permits that individual to interact effectively with health care providers or plan employees.

(4) Point of Contact: an instance in which an enrollee accesses the services covered under the plan contract, including administrative and clinical services, and telephonic and in-person contacts.

(5) Threshold Language(s): the language(s) identified by a plan pursuant to Section 1367.04(b)(1)(A) of the Act.

(6) Translation: replacement of a written text from one language (source language) with an equivalent written text in another language (target language).

(7) Vital Documents: the following documents, when produced by the plan (plan-produced documents) including when the production or distribution is delegated by a plan to a contracting health care service provider or administrative services provider:

(A) Applications;

(B) Consent forms, including any form by which an enrollee authorizes or consents to any action by the plan;

(C) Letters containing important information regarding eligibility and participation criteria;

(D) Notices pertaining to the denial, reduction, modification, or termination of services and benefits, and the right to file a grievance or appeal;

(E) Notices advising LEP enrollees of the availability of free language assistance and other outreach materials that are provided to enrollees;

(F) A plan's explanation of benefits or similar claim processing information that is sent to an enrollee if the document requires a response from the enrollee; and

(G) Subject to subsection (c)(2)(F)(ii), the enrollee disclosures required by Section 1363(a)(1), (2) and (4) of the Act.

(c) Language Assistance Program Requirements.

Every plan shall develop and implement a language assistance program, which shall comply with the requirements and standards established by Section 1367.04 of the Act and this section. The language assistance program shall be documented in written policies and procedures, and shall address, at a minimum, the following four elements: standards for enrollee assessment; standards for providing language assistance services; standards for staff training; and standards for compliance monitoring.

(1) Enrollee Assessment. Every health care service plan and specialized health care service plan shall assess its enrollee population to develop a demographic profile and to survey the linguistic needs of individual enrollees. In assessing its enrollee population each plan shall, at a minimum:

(A) Develop a demographic profile of the plan's enrollee population for the purposes of calculating threshold languages and reporting to the Department pursuant to Section 1367.07 of the Act. All plans shall apply statistically valid methods for population analysis in developing the

demographic profile and plans may utilize a variety of methods for collecting demographic data for this purpose, including census data, client utilization data from third parties, data from community agencies and third party enrollment processes;

(B) Survey its enrollees in a manner designed to identify the linguistic needs of each of the plan's enrollees, and record the information provided by a responding enrollee in the enrollee's file. Plans may utilize existing processes and methods to distribute the linguistic needs survey, including but not limited to, existing enrollment and renewal processes, subscriber newsletters, mailings and other communication processes. A plan may demonstrate compliance with the survey requirement by distributing to all subscribers, including all individual subscribers under group contracts, a disclosure explaining, in English and in the plan's threshold languages, the availability of free language assistance services and how to inform the plan and relevant providers regarding the preferred spoken and written languages of the subscriber and other enrollees under the subscriber contract; and

(C) Collect, summarize and document enrollee demographic profile data in a manner that enables the plan to maintain confidentiality of personal information and to disclose the information to the Department on request for regulatory purposes and to contracting providers on request for lawful purposes, including language assistance purposes and health care quality improvement purposes. This section is not intended to limit or expand existing law regarding confidentiality of medical records.

(2) Providing Language Assistance Services. Every plan shall develop language assistance program policies and procedures, which shall describe, at a minimum, the information outlined below.
(A) All points of contact where the need for language assistance may be reasonably anticipated.

(B) The types of resources needed to provide effective language assistance to the plan's enrollees.

(C) The plan's processes for informing enrollees of the availability of language assistance services at no charge to enrollees, and how to access language assistance services. At a minimum, these processes shall include the following:

(i) Processes to promote effective identification of LEP enrollee language assistance needs at points of contact, to ensure that LEP enrollees are informed at points of contact that interpretation services are available at no cost to the LEP enrollee, and to facilitate individual enrollee access to interpretation services at points of contact.

(ii) Processes for including the notice required by Section 1367.04(b)(1)(B)(v) with all vital documents, all enrollment materials and all correspondence, if any, from the plan confirming a new or renewed enrollment. If documents are distributed in an LEP enrollee's preferred written language the notice need not be included.

(iii) Processes for including statements, in English and in threshold languages, about the availability of free language assistance services and how to access them, in or with brochures, newsletters, outreach and marketing materials and other materials that are routinely disseminated to the plan's enrollees.

(D) Processes to ensure the plan's language assistance program conforms with the requirements of section 1300.68(b)(3) and (7) of these regulations, including standards to ensure that LEP enrollees receive information regarding their rights to file a grievance and seek an independent medical review in threshold languages and through oral interpretation.

(i) All plans shall ensure that grievance forms and procedures in threshold languages are made readily available to enrollees and to contracting providers for distribution to enrollees upon request.

(ii) All plans shall inform contracting providers that informational notices explaining how enrollees may contact their plan, file a complaint with their plan, obtain assistance from the Department and seek an independent medical review are available in non-English languages through the Department's web site. The notice and translations can be obtained online at www.hmohelp.ca.gov for downloading and printing. In addition, hard copies may be requested by submitting a written request to: Department of Managed Health Care, Attention: HMO Help Notices, 980 9th Street, Suite 500, Sacramento, CA 95814.

(E) Processes to ensure that contracting providers are informed regarding the plan's standards and mechanisms for providing language assistance services at no charge to enrollees, and to ensure that LEP language needs information collected by the plan is made available to contracting providers.

(F) Processes and standards for providing translation services, including, but not limited to:

(i) A list of the threshold languages identified by the plan;

(ii) A list of the types of standardized and enrollee-specific vital documents that must be translated and the applicable standards for making translated vital documents available to subscribers and enrollees. Plans need not translate subscriber contracts, evidences of coverage and other large disclosure forms and enrollee handbooks in their entirety, but may excerpt from large documents the disclosures specified at subsection (b)(7)(G) for translation in a format that permits cost-effective and timely production and distribution, so long as there is no loss of accuracy or meaning by doing so. A plan may demonstrate compliance regarding translation of the disclosures specified at subsection (b)(7)(G) if the plan provides a standardized matrix that lists the major categories of health care services covered under the plan's subscriber contracts, together with the corresponding copayments and coinsurance, and exclusions and limitations, and disclosing any applicable deductibles and lifetime maximums, using the same sequence as the uniform matrix described at Section 1363(b)(1) of the Act.

(iii) A description of how the plan will provide or arrange for the provision of translation of vital documents at no charge to enrollees in accordance with the requirements of Section 1367.04 of the Act and this section. This subsection is not intended to prohibit or discourage a plan from providing translation of vital documents into a greater number of languages than the threshold languages;

(iv) A requirement that non-English translations of vital documents must meet the same standards required for English language versions of those documents; and

(v) A requirement that, with respect to vital documents that are not standardized, but which contain enrollee-specific information, a plan shall provide the English version together with the Department-approved written notice of the availability of interpretation and translation services and, if a translation is requested, the plan shall provide the requested translation in accordance with the requirements of Section 1367.04 of the Act and this section.

(G) Processes and standards for providing individual enrollee access to interpretation services at points of contact at no charge, including, but not limited to:

(i) A list of the non-English languages likely to be encountered among the plan's enrollees.

(ii) A requirement that the plan shall provide LEP enrollees with interpretation services for information contained in plan-produced documents.

(iii) A requirement that qualified interpretation services be offered to LEP enrollees, at no cost to the enrollee, at all points of contact, including when an enrollee is accompanied by a family member or friend that can provide interpretation services. The offer of a qualified interpreter, and the enrollee's refusal if interpretation services are declined, shall be documented in the medical record or plan file, as applicable.

(iv) When an enrollee needs interpretation services at a point of contact that occurs in a hospital, facility or provider office subject to federal or state law that requires the hospital, facility or provider office to provide interpretation services, the plan is not relieved of its obligation to comply with the requirements of Section 1367.04 of the Act or this section. Full service plans shall have reasonable processes in place to ensure that LEP enrollees can obtain the plan's assistance in arranging for the provision of timely interpretation services at all points of contact as defined at subsection (b)(4). This subsection does not prohibit a plan from incorporating into its language assistance program a contracting hospital's language assistance program if: the hospital's language assistance program provides access to interpretation services consistent with the requirements of Section 1367.04 of the Act and this section; the plan monitors for deficiencies in delivery of interpretation services by the hospital; and the plan takes appropriate corrective action to address hospital deficiencies in delivery of interpretation services to the plan's enrollees. This subsection is not intended to limit or expand any existing state or federal law.

(v) A description of the arrangements the plan will make to provide or arrange for the provision of timely interpretation services at no charge to LEP enrollees at all points of contact where language assistance is needed. For purposes of this subsection "timely" means in a manner appropriate for the situation in which language assistance is needed. Interpretation services are not timely if delay results in the effective denial of the service, benefit, or right at issue. A plan's language assistance program shall specify quality assurance standards for timely delivery of language assistance services for emergency, urgent and routine health care services, and shall include standards for coordinating interpretation services with appointment scheduling.

(vi) The range of interpretation services that will be provided to enrollees as appropriate for the particular point of contact. The range of services may include, but is not limited to:

(aa) Arranging for the availability of bilingual plan or provider staff who are trained and competent in the skill of interpreting;

(bb) Hiring staff interpreters who are trained and competent in the skill of interpreting;

(cc) Contracting with an outside interpreter service for trained and competent interpreters;

(dd) Arranging formally for the services of voluntary community interpreters who are trained and competent in the skill of interpreting; and

(ee) Contracting for telephone, videoconferencing or other telecommunications supported language interpretation services.

(vii) As used in this section, "trained and competent in the skill of interpreting," "qualified interpretation services" and "qualified interpreter" means that the interpreter meets the plan's proficiency standards established pursuant to subsection (c)(2)((H).

(H) The plan's policies and standards for ensuring the proficiency of the individuals providing translation and interpretation services. A plan may develop and apply appropriate criteria for ensuring the proficiency of translation and interpretation services or may adopt certification by an association acceptable to the Department at the time of certification. A plan's language assistance proficiency standards shall require:

(i) A documented and demonstrated proficiency in both English and the other language;

(ii) A fundamental knowledge in both languages of health care terminology and concepts relevant to health care delivery systems; and

(iii) Education and training in interpreting ethics, conduct and confidentiality. The Department will accept plan standards for interpreter ethics, conduct, and confidentiality that adopt and apply, in full, the standards promulgated by the California Healthcare Interpreters Association or the National Council on Interpreting in Healthcare.

(3) Staff training.

Every plan shall implement a system to provide adequate training regarding the plan's language assistance program to all plan staff who have routine contact with LEP enrollees. The training shall include instruction on:

(A) Knowledge of the plan's policies and procedures for language assistance;

(B) Working effectively with LEP enrollees;

(C) Working effectively with interpreters in person and through video, telephone and other media, as may be applicable; and

(D) Understanding the cultural diversity of the plan's enrollee population and sensitivity to cultural differences relevant to delivery of health care interpretation services.

(4) Compliance Monitoring.

(A) Every plan shall monitor its language assistance program, including delegated programs, and make modifications as necessary to ensure compliance with Section 1367.04 of the Act and this section.

(d) In reviewing a plan's proposed language assistance program, the Department will evaluate the totality of the plan's language assistance program to determine whether the program as a whole provides meaningful access for LEP enrollees, and may consider relevant operational and demographic factors, including but not limited to:

(1) Whether the plan is a full service plan or specialized health care service plan;

(2) The nature of the points of contact;

(3) The frequency with which particular languages are encountered;

(4) The type of provider network and methods of health care service delivery;

(5) The variations and character of a plan's service area;

(6) The availability of translation and interpretation services and professionals;

(7) The variations in cost of language assistance services and the impact on affordability of health care coverage; and

(8) A plan's implementation of best practices and utilization of existing and emerging technologies to increase access to language assistance services, such as video interpreting

programs, language translation software, collaborating with other plans to share a pool of interpreters, and other methods and technologies.

(9) Specialized dental, vision, chiropractic, acupuncture and employee assistance program plans that demonstrate adequate availability and accessibility of qualified bilingual contracted providers and office staff to provide meaningful access to LEP enrollees, will be in compliance with the requirements of subsection (c)(2)(G)(iii) and (v). For the purposes of this subsection, specialized dental, vision, chiropractic, acupuncture and employee assistance program plans may demonstrate adequate availability and accessibility of competent and qualified bilingual providers and office staff if:

A) The plan identifies within its provider directories those contracting providers who are themselves bilingual or who employ other bilingual providers and/or office staff, based on language capability disclosure forms signed by the bilingual providers and/or office staff, attesting to their fluency in languages other than English;

B) The plan requires all contracting providers to provide quarterly updates regarding any changes in the language capabilities of currently employed providers and/or office staff by submitting new language capability disclosure forms, and the plan updates its provider directories accordingly, and consistent with Section 1367.26 of the Act; and

C) The plan's quality assurance audits of contracting providers confirm and document the accuracy of provider language capability disclosure forms and attestations.

(e) Implementation.

(1) Within one year of the effective date of this section, every plan shall complete the initial enrollee assessment required by Section 1367.04 of the Act and this section. Every plan shall update its assessment of enrollee language needs and enrollee demographic profile at least once every three years following the initial assessment.

(2) By July 1, 2008, every plan shall file, in accordance with Section 1352 of the Act, an amendment to its quality assurance program providing its written language assistance program policies and procedures, together with information and documents sufficient to demonstrate compliance with the requirements and standards of Section 1367.04 of the Act and this section. The filing shall include the plan's Section 1367.04(b)(1)(B)(v) notices. All materials filed with the Department that contain documents in non-English languages shall include the following minimum supporting documentation:

(i) The English version of each non-English document.

(ii) An attestation by the translator or, if applicable, by an authorized officer of the organization providing translator services, outlining the qualifications of the translator making the translation and affirming that the non-English translation is an accurate translation of the English version.

(3) By January 1, 2009 every plan shall have established and implemented a language assistance program in compliance with the requirements of Section 1367.04 of the Act and this section.

(4) Every contract between a health care provider and a plan, including a specialized plan, that is issued, amended, delivered or renewed on or after January 1, 2009, shall require compliance with the plan's language assistance program standards developed pursuant to Section 1367.04 of the Act and this section.

(A) A plan shall retain financial responsibility for the implementation of the language assistance program required by Section 1367.04 of the Act and this section, except to the extent that delegated financial responsibility has been separately negotiated and specifically documented in written contracts. This subsection does not create an exception to Section 1367 of the Act and delegation shall not constitute a waiver of the plan's obligation to provide language assistance services required by Section 1367.04 of the Act and this section.

(B) Delegation to contracting providers of any part of the plan's obligation to provide language assistance services required by Section 1367.04 of the Act and this section constitutes a material change to a provider contract subject to the requirements of Section 1375.7 of the Act.

(f) The Department will periodically review plan compliance with the standards and requirements of Section 1367.04 of the Act and this section by methods that may include, but are not limited to, the medical survey process, reviews of consumer grievances and complaints to the Department's HMO Help Center, and provider complaints submitted to the Department's provider complaint line. The Department may also periodically request that plans submit information and data regarding enrollee language needs and demographic profile.

§ 1300.74.30. Independent Medical Review System

(a) Plan enrollees may request independent medical review pursuant to this regulation for decisions that are eligible for independent medical review under Article 5.55 and section 1370.4 of the Act. The independent medical review process shall resolve decisions that deny, modify, or delay health care services, that deny reimbursement for urgent or emergency services or that involve experimental or investigational therapies. Specialized plans shall provide for independent medical reviews under this section if a covered service relates to the practice of medicine or is provided pursuant to a contract with a health plan providing medical, surgical and hospital services. The Department shall be the final arbiter when there is a question as to whether a dispute over a health care service is eligible for independent medical review, and whether extraordinary and compelling circumstances exist that waive the requirement that the enrollee first participate in the plan's grievance system.

(b) An enrollee may apply for an independent medical review under the conditions specified in Section 1374.30(j) of the Act. The Department may waive the requirement that the enrollee participate in the plan's grievance process if the Department determines that extraordinary and compelling circumstances exist, which include, but are 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.

(c) In cases involving a claim for out of plan emergency or urgent services that a provider determined were medically necessary, the independent medical review shall determine whether the services were emergency or urgent services necessary to screen and stabilize the enrollee's condition. For purposes of this section "emergency services" are services for emergency medical conditions as defined in section 1300.71.4 of title 28, and "urgent services" are all services, except emergency services, where the enrollee has obtained the services without prior authorization from the plan, or from a contracting provider.

(d) Applications for independent medical review shall be submitted on a one-page form entitled Independent Medical Review Application (DMHC IMR 11/00), which is incorporated by reference, and shall be provided by the Department. The form shall contain a signed release from the enrollee, or a person authorized pursuant to law to act on behalf of the enrollee, authorizing release of medical and treatment information. Additionally, the enrollee may provide any relevant material or documentation with the application including, but not limited to:

(1) A copy of the adverse determination by the plan or contracting provider notifying the enrollee that the request for health care services was denied, delayed or modified, in whole or in part, based on the determination that the service was not medically necessary;

(2) Medical records, statements from the enrollee's provider or other documents establishing that the dispute is eligible for review;

(3) A copy of the grievance requesting the health care service, or benefit filed with the plan or any entity with delegated authority to resolve grievances, and the response to the grievance, if any;

(4) If expedited review is requested for a decision eligible for independent medical review pursuant to Article 5.55 of the Act, the application shall include, a certification from the enrollee's physician or provider indicating that an imminent and serious threat to the health of the enrollee exists. If expedited review is requested for a decision eligible for independent medical review pursuant to section 1370.4 of the Act, the application shall include a certification from the enrollee's physician that the proposed therapy would be significantly less effective if not promptly initiated.

(e) If additional information is needed to complete an application or to determine the enrollee's eligibility for independent medical review, the Department shall advise the enrollee or the enrollee's representative, the enrollee's provider, the enrollee's health care plan or the enrollee's attending physician, as appropriate, by the most efficient means available.

(f) The Department shall evaluate complaints received under subsection (b) of Section 1368 of the Act and applications submitted under this regulation and determine whether the enrollee is eligible for an independent medical review. The Department's determination will consider all

information provided to the Department, the enrollee's medical condition and the disputed health care service. If the Department determines that the case should not be referred to independent medical review, the request shall be considered a complaint under subsection (b) of Section 1368 and sections 1300.68 and 1300.68.01. The enrollee or the enrollee's representative, health plan and any involved provider shall be advised of the Department's determination.

(1) The request for independent medical review shall be filed with the Department within six months of the plan's written response to the enrollee's grievance. The six-month period does not begin to run until the enrollee, or the enrollee's representative, has been properly notified in writing of the plan's resolution of the grievance. Applications will not be rejected as untimely solely because the enrollee, the enrollee's provider, or the plan failed to submit supporting documentation. Requests for extensions or late applications shall be approved if a timely submission was reasonably impaired by inadequate notice of the independent medical review process or by the applicant's medical circumstances.

(2) An application will not be eligible for independent medical review if the enrollee's complaint has previously been submitted and reviewed by the Department. Exceptions may be approved if the application for independent medical review includes medical records and a statement from the enrollee's physician or provider demonstrating significant changes in the enrollee's medical condition or in medical therapies available have occurred since the Department's disposition of the complaint.

(3) Enrollees of Medi-Cal health care service plans are eligible for an independent medical review if the enrollee has not presented the disputed health care service for resolution by the Medi-Cal fair hearing process. Reviews shall be conducted in accordance with the statutes and regulations of the Medi-Cal program.

(4) This regulation applies to Medicare enrollees, to the extent the regulation does not conflict with federal law, including 42 USCS § 1395w-26 (2004).

(g) Except for Medi-Cal enrollees, and Medicare enrollees exempted by federal law, as described at subsection (f)(4), the independent medical review system established pursuant to this section shall be the exclusive independent medical review process offered to enrollees for disputes involving the medical necessity of covered health care services. Nothing in this section shall preclude a health plan from offering other independent review processes for disputes that do not involve medical necessity.

(h) When the Department finds that a plan fails to advise an enrollee of the availability of independent medical review as required under Health and Safety Code section 1374.30(i), or engages in a practice of mischaracterizing determinations substantially based on medical necessity as coverage decisions, or otherwise interferes with the rights of enrollees to obtain independent medical review, the Department shall impose administrative penalties on the plan in accordance with the Act.

(i) The director shall notify the enrollee and the enrollee's health care plan if an application for independent medical review has been accepted within seven (7) calendar days of receipt of a completed application for a routine request and within 48 hours of receipt of a completed application for an expedited review. The notification shall identify the independent medical review organization, whether the review shall be conducted on an expedited or routine basis and other information deemed necessary by the Department. The director shall also transmit to the enrollee's health care plan a copy of the enrollee's signed release of medical and treatment information and copies of all other materials submitted with the enrollee's, application.

(j) Following receipt of the Department's notification that an application for independent medical review has been assigned to an independent medical review organization, the plan shall provide the organization with all information that was considered in relation to the disputed health care service, the enrollee's grievance and the plan's determination. The plan shall forward all information to the medical review organization within three (3) business days for a regular review and within one (1) calendar day in the case of an expedited review.

(1) Unless otherwise advised in the notification or by the assigned review organization, the plan shall submit a complete set of the materials described below for the independent review organization.

(A) A copy of all correspondence from and received by the plan concerning the disputed health care service, including but not limited to, any enrollee grievance relating to the requested service;

(B) A complete and legible copy of all medical records and other information used by the plan in making its decision regarding the disputed health care service. An additional copy of medical records shall be submitted for each reviewer.

(C) A copy of the cover page of the evidence of coverage and complete pages with the referenced sections highlighted or underlined sections, if the evidence of coverage was referenced in the plan's resolution of the enrollee's grievance;

(D) The plan's response to any additional issues raised in the enrollee's application for independent medical review.

(2) The plan shall promptly provide the enrollee with an annotated list of all documents submitted to the independent medical review organization, together with information on how copies may be requested.

(k) Plans shall be responsible for providing additional information as follows:

(1) Any medical records or other relevant matters not available at the time of the Department's initial notification, or that result from the enrollee's on-going medical care or treatment for the medical condition or disease under review. Such matters shall be forwarded as soon as possible upon receipt by the health plan, not to exceed five (5) business days in routine cases or one (1) calendar day in expedited cases.

(2) Additional medical records or other information requested by the IMR organization shall be sent within five (5) business days in routine cases or one (1) calendar day in expedited cases. In expedited reviews, the health care plan shall immediately notify the enrollee and the enrollee's health care provider by telephone or facsimile to identify and request the necessary information, followed by written notification, when the request involves materials not in the possession of the plan or its contracting providers.

(l) Each assigned reviewer shall issue a separate written analysis of the case, explaining the determination made, using plain English where possible. The analysis shall describe how the determination relates to the enrollee's medical condition and history, relevant medical records and other documents considered, and references to the specific medical and scientific evidence listed in Sections 1370.4(d) or 1374.33(b) of the Act, as applicable. For requests made pursuant to Article 5.55 of the Act, reviewers shall determine whether the disputed service is medically necessary for the enrollee. For requests made pursuant to section 1370.4 of the Act, the reviewers shall determine whether the requested therapy is likely to be more beneficial for the enrollee then other available standard therapies, and whether the plan shall provide the requested therapy. Reviews based on section 1300.70.4 of these regulations shall also reference the medical and scientific evidence considered in assessing whether the requested health care service is likely to be more beneficial than other available standard therapies. The analysis may also discuss the risks and benefits considered by the reviewer in considering proposed and standard treatments.

(m) The Department, the enrollee, or his/her representative may withdraw a case from the independent review system at any time. The plan may seek withdrawal of the case from the review system by providing the disputed health care service, subject to the concurrence of the enrollee.

RELEVANT CALIFORNIA LAW REGARDING THE EXTERNAL REVIEW PROCESS:

KNOX-KEENE ACT PROVISIONS:

§ 1374.30. Establishment of system; participation; conditions for application for independent review; forms

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

(b) For the purposes of this chapter, "disputed health care service" means any health care service eligible for coverage and payment under a health care service plan contract that has been denied, modified, or delayed by a decision of the plan, or by one of its contracting providers, in whole or in part due to a finding that the service is not medically necessary. A decision regarding a disputed health care service relates to the practice of medicine and is not a coverage decision. A disputed health care service does not include services provided by a specialized health care service plan, except to the extent that the service (1) involves the practice of medicine, or (2) is provided pursuant to a contract with a health care service plan that covers hospital, medical, or surgical benefits. If a plan, or one of its contracting providers, issues a decision denying, modifying, or delaying health care services, based in whole or in part on a finding that the proposed health care services are not a covered benefit under the contract that applies to the enrollee, the statement of decision shall clearly specify the provision in the contract that excludes that coverage.

(c) For the purposes of this chapter, "coverage decision" means the approval or denial of health care services by a plan, or by one of its contracting entities, substantially based on a finding that the provision of a particular service is included or excluded as a covered benefit under the terms and conditions of the health care service plan contract. A "coverage decision" does not encompass a plan or contracting provider decision regarding a disputed health care service.

(d)(1) All enrollee grievances involving a disputed health care service are eligible for review under the Independent Medical Review System if the requirements of this article are met. If the department finds that an enrollee grievance involving a disputed health care service does not meet the requirements of this article for review under the Independent Medical 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, including grievances involving coverage decisions, remain eligible for review by the department pursuant to subdivision (b) of Section 1368.

(2) In any case in which an enrollee or provider asserts that a decision to deny, modify, or delay health care services was based, in whole or in part, on consideration of medical necessity, the department shall have the final authority to determine whether the grievance is more properly resolved pursuant to an independent medical review as provided under this article or pursuant to subdivision (b) of Section 1368.

(3) The department shall be the final arbiter when there is a question as to whether an enrollee grievance is a disputed health care service or a coverage decision. The department shall establish a process to complete an initial screening of an enrollee grievance. If there appears to be any medical necessity issue, the grievance shall be resolved pursuant to an independent medical review as provided under this article or pursuant to subdivision (b) of Section 1368.

(e) Every health care service plan contract that is issued, amended, renewed, or delivered in this state on or after January 1, 2000, shall, effective January 1, 2001, provide an enrollee with the opportunity to seek an independent medical review whenever health care services have been denied, modified, or delayed by the plan, or by one of its contracting providers, if the decision was based in whole or in part on a finding that the proposed health care services are not medically necessary. For purposes of this article, an enrollee may designate an agent to act on his or her behalf, as described in paragraph (2) of subdivision (b) of Section 1368. The provider may join with or otherwise assist the enrollee in seeking an independent medical review, and may advocate on behalf of the enrollee.

(f) Medi-Cal beneficiaries enrolled in a health care service plan shall not be excluded from participation. Medicare beneficiaries enrolled in a health care service plan shall not be excluded unless expressly preempted by federal law. Reviews of cases for Medi-Cal enrollees shall be conducted in accordance with statutes and regulations for the Medi-Cal program.

(g) The department may seek to integrate the quality of care and consumer protection provisions, including remedies, of the Independent Medical 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.

(h) The independent medical review process authorized by this article is in addition to any other procedures or remedies that may be available.

(i) No later than January 1, 2001, every health care service plan shall prominently display in every plan member handbook or relevant informational brochure, in every plan contract, on enrollee evidence of coverage forms, on copies of plan procedures for resolving grievances, on letters of denials issued by either the plan or its contracting organization, on the grievance forms required under Section 1368, and on all written responses to grievances, information concerning the right of an enrollee to request an independent medical review in cases where the enrollee believes that health care services have been improperly denied, modified, or delayed by the plan, or by one of its contracting providers.

(j) An enrollee may apply to the department for an independent medical review when all of the following conditions are met:

(1)(A) The enrollee's provider has recommended a health care service as medically necessary, or

(B) The enrollee has received urgent care or emergency services that a provider determined was medically necessary, or

(C) The enrollee, in the absence of a provider recommendation under subparagraph (A) or the receipt of urgent care or emergency services by a provider under subparagraph (B), has been seen by an in-plan provider for the diagnosis or treatment of the medical condition for which the enrollee seeks independent review. The plan shall expedite access to an in-plan provider upon request of an enrollee. The in-plan provider need not recommend the disputed health care service as a condition for the enrollee to be eligible for an independent review.

For purposes of this article, the enrollee's provider may be an out-of-plan provider. However, the plan shall have no liability for payment of services provided by an out-of-plan provider, except as provided pursuant to subdivision (c) of Section 1374.34.

(2) The disputed health care service has been denied, modified, or delayed by the plan, or by one of its contracting providers, based in whole or in part on a decision that the health care service is not medically necessary.

(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 to the department for an independent medical review of a decision to deny, modify, or delay health care services, based in whole or in part on a finding that the disputed health care services are not medically necessary, within six months of any of the qualifying periods or events under subdivision (j). The director may extend the application deadline beyond six months if the circumstances of a case warrant the extension.

(l) The enrollee shall pay no application or processing fees of any kind.

(m) As part of its notification to the enrollee regarding a disposition of the enrollee's grievance that denies, modifies, or delays health care services, the plan shall provide the enrollee with a one-page application form approved by the department, and an addressed envelope, which the enrollee may return to initiate an independent medical review. The plan shall include on the form any information required by the department to facilitate the completion of the independent medical review, such as the enrollee's diagnosis or condition, the nature of the disputed health care service sought by the enrollee, a means to identify the enrollee's case, and any other material information. The form shall also include the following:

(1) Notice that a decision not to participate in the independent medical review process may cause the enrollee to forfeit any statutory right to pursue legal action against the plan regarding the disputed health care service.

(2) A statement indicating the enrollee's 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, to be signed by the enrollee.

(3) Notice of the enrollee's right to provide information or documentation, either directly or through the enrollee's provider, regarding any of the following:

(A) A provider recommendation indicating that the disputed health care service is medically necessary for the enrollee's medical condition.

(B) Medical information or justification that a disputed health care service, on an urgent care or emergency basis, was medically necessary for the enrollee's medical condition.

(C) Reasonable information supporting the enrollee's position that the disputed health care service is or was medically necessary for the enrollee's medical condition, including 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 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.

(n) Upon notice from the department that the health care service plan's enrollee has applied for an independent medical review, the plan or its contracting providers shall provide to the independent medical review organization designated by the department a copy of all of the following documents within three business days of the plan's receipt of the department's notice of a request by an enrollee for an independent review:

(1)(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.

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

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

(B) Any newly developed or discovered relevant medical records in the possession of the plan or its contracting providers after the initial documents are provided to the independent medical review organization shall be forwarded immediately to the independent medical review organization. The plan shall concurrently provide a copy of medical records required by this

subparagraph to the enrollee or the enrollee's provider, if authorized by the enrollee, 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.

(2) A copy of all information provided to the enrollee by the plan and any of its contracting providers concerning plan and provider decisions regarding the enrollee's condition and care, 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 request for disputed health care services. This documentation shall include the written response to the enrollee's grievance, required by paragraph (4) of subdivision (a) of Section 1368. The confidentiality of any enrollee medical information shall be maintained pursuant to applicable state and federal laws.

(3) A copy of any other relevant documents or information used by the plan or its contracting providers in determining whether disputed health care services should have been provided, and any statements by the plan and its contracting providers explaining the reasons for the decision to deny, modify, or delay disputed health care services on the basis of medical necessity. The plan shall concurrently provide a copy of documents required by this paragraph, except for any information found by the director 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 director to be the proprietary information of the plan.

§ 1374.31. Imminent threat to health; expeditious review

(a) If there is an imminent and serious threat to the health of the enrollee, as specified in subdivision (c) of Section 1374.33, all necessary information and documents shall be delivered to an independent medical review organization within 24 hours of approval of the request for review. In reviewing a request for review, the department may waive the requirement that the enrollee follow the plan's grievance process in extraordinary and compelling cases, where the director finds that the enrollee has acted reasonably.

(b) The department shall expeditiously review requests and immediately notify the enrollee in writing as to whether the request for an independent medical review has been approved, in whole or in part, and, if not approved, the reasons therefore. The plan shall promptly issue a notification to the enrollee, after submitting all of the required material to the independent medical review organization that includes an annotated list of documents submitted and offer the enrollee the opportunity to request copies of those documents from the plan. The department shall promptly approve enrollee requests whenever the enrollee's plan has agreed that the case is eligible for an independent medical review. The department shall not refer coverage decisions for independent review. To the extent an enrollee request for independent review is not approved by the department, the enrollee request shall be treated as an immediate request for the department to review the grievance pursuant to subdivision (b) of Section 1368.

(c) An independent medical review organization, specified in Section 1374.32, shall conduct the review in accordance with Section 1374.33 and any regulations or orders of the director adopted

pursuant thereto. The organization's review shall be limited to an examination of the medical necessity of the disputed health care services and shall not include any consideration of coverage decisions or other contractual issues.

§ 1374.32. Medical review organizations

(a) By January 1, 2001, the department shall contract with one or more independent medical review organizations in the state to conduct reviews for purposes of this article. The independent medical review organizations shall be independent of any health care service plan doing business in this state. The director may establish additional requirements, including 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 Medical Review System and to assist the department in carrying out its responsibilities.

(b) The independent medical review organizations and the medical professionals retained to conduct reviews shall be deemed to be medical consultants for purposes of Section 43.98 of the Civil Code.

(c) The independent medical review organization, any experts it designates to conduct a review, or any officer, director, or employee of the independent medical review organization shall not have any material professional, familial, or financial affiliation, as determined by the director, with any of the following:

(1) The plan.

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

(3) A physician, the physician's medical group, or the independent practice association involved in the health care service in dispute.

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

(5) 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.

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

(d) In order to contract with the department for purposes of this article, an independent medical review organization shall meet all of the following requirements:

(1) The 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 medical 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 medical review organization.

(2) The organization shall submit to the department the following information upon initial application to contract for purposes of this article 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 medical 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 medical 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 medical 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 medical 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 medical review organization uses to identify and recruit medical professionals to review treatment and treatment recommendation decisions, the number of medical professionals credentialed, and the types of cases and areas of expertise that the medical professionals are credentialed to review.

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

(3) The 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.

(B) Ensures that the reviews provided by the medical professionals 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 for individual cases achieves a fair and impartial panel of medical professionals who are qualified to render recommendations regarding the clinical conditions and the medical necessity of treatments or therapies in question.

(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 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 medical 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 and protocols in the area of treatment under review.

(B) Notwithstanding any other provision of law, the medical professional shall hold a non-restricted license in any state of the United States, 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. The independent medical review organization shall give preference to the use of a physician licensed in California as the reviewer, except when training and experience with the issue under review reasonably requires the use of an out-of-state reviewer.

(C) The medical professional 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 medical 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 medical

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 medical 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 medical review organization or individual to which this subdivision applies. "Material financial affiliation" does not include payment by the plan to the independent medical 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 department shall provide, upon the request of any interested person, a copy of all nonproprietary information, as determined by the director, filed with it by an independent medical review organization seeking to contract under this article. The department may charge a nominal fee to the interested person for photocopying the requested information.

§ 1374.33. Analysis and determination

(a) Upon receipt of information and documents related to a case, the medical professional reviewer or reviewers selected to conduct the review by the independent medical 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. The reviewer or reviewers shall also review relevant information related to the criteria set forth in subdivision (b).

(b) Following its review, the reviewer or reviewers shall determine whether the disputed health care service was medically necessary based on the specific medical needs of the enrollee and any of the following:

(1) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service.

(2) Nationally recognized professional standards.

(3) Expert opinion.

(4) Generally accepted standards of medical practice.

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

(c) The organization shall complete its review and make its determination in writing, and in layperson's terms to the maximum extent practicable, within 30 days of the receipt of the application for review and supporting documentation, or within less time as prescribed by the director. If the disputed health care service 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 receipt of the information. Subject to the approval of the department, the deadlines for analyses and determinations involving both regular and expedited reviews may be extended by the director for up to three days in extraordinary circumstances or for good cause.

(d) The medical professionals' analyses and determinations shall state whether the disputed health care service is medically necessary. Each analysis shall cite the enrollee's medical condition, the relevant documents in the record, and the relevant findings associated with the provisions of subdivision (b) to support the determination. If more than one medical professional reviews the case, the recommendation of the majority shall prevail. If the medical professionals reviewing the case are evenly split as to whether the disputed health care service should be provided, the decision shall be in favor of providing the service.

(e) The independent medical review organization shall provide the director, the plan, the enrollee, and the enrollee's provider with the analyses and determinations of the medical professionals reviewing the case, and a description of the qualifications of the medical

professionals. The independent medical review organization shall keep the names of the reviewers confidential in all communications with entities or individuals outside the independent medical review organization, except in cases where the reviewer is called to testify and in response to court orders. If more than one medical professional reviewed the case and the result was differing determinations, the independent medical review organization shall provide each of the separate reviewer's analyses and determinations.

(f) The director shall immediately adopt the determination of the independent medical review organization, and shall promptly issue a written decision to the parties that shall be binding on the plan.

(g) After removing the names of the parties, including, but not limited to, the enrollee, all medical providers, the plan, and any of the insurer's employees or contractors, director decisions adopting a determination of an independent medical review organization shall be made available by the department to the public upon request, at the department's cost and after considering applicable laws governing disclosure of public records, confidentiality, and personal privacy.

§ 1374.34. Prompt implementation of decision; review and audit

(a) Upon receiving the decision adopted by the director pursuant to Section 1374.33 that a disputed health care service is medically necessary, the plan shall promptly implement the decision. In the case of reimbursement for services already rendered, the plan shall reimburse the provider or enrollee, whichever applies, within five working days. In the case of services not yet rendered, the plan shall authorize the services within five working days of receipt of the written decision from the director, or sooner if appropriate for the nature of the enrollee's medical condition, and shall inform the enrollee and provider of the authorization in accordance with the requirements of paragraph (3) of subdivision (h) of Section 1367.01.

(b) A plan shall not engage in any conduct that has the effect of prolonging the independent review process. The engaging in that conduct or the failure of the plan to promptly implement the decision is a violation of this chapter and, in addition to any other fines, penalties, and other remedies available to the director under this chapter, the plan shall be subject to an administrative penalty of not less than five thousand dollars ($5,000) for each day that the decision is not implemented. The administrative penalties shall be paid to the Managed Care Administrative Fines and Penalties Fund and shall be used for the purposes specified in Section 1341.45.

(c) The director shall require the plan to promptly reimburse the enrollee for any reasonable costs associated with those services when the director finds that the disputed health care services were a covered benefit under the terms and conditions of the health care service plan contract, and the services are found by the independent medical review organization to have been medically necessary pursuant to Section 1374.33, and either the enrollee's decision to secure the services outside of the plan provider network was reasonable under the emergency or urgent medical circumstances, or the health care service plan contract does not require or provide prior authorization before the health care services are provided to the enrollee.

(d) In addition to requiring plan compliance regarding subdivisions (a), (b), and (c) the director shall review individual cases submitted for independent medical review to determine whether any enforcement actions, including penalties, may be appropriate. In particular, where substantial harm, as defined in Section 3428 of the Civil Code, to an enrollee has already occurred because of the decision of a plan, or one of its contracting providers, to delay, deny, or modify covered health care services that an independent medical review determines to be medically necessary pursuant to
Section 1374.33, the director shall impose penalties.

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

§ 1374.35. Reimbursement of costs

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

(b) The costs of the independent medical review system for enrollees shall be borne by health care service plans pursuant to an assessment fee system established by the director. In determining the amount to be assessed, the director shall consider all appropriations available for the support of this chapter, and existing fees paid to the department. The director may adjust fees upward or downward, on a schedule set by the department, to address shortages or overpayments, and to reflect utilization of the independent review process.

§ 1374.36. Report on implementation of article

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

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

CALIFORNIA CODE OF REGULATION PROVISIONS:

§ 1300.74.30. Independent Medical Review System

(a) Plan enrollees may request independent medical review pursuant to this regulation for decisions that are eligible for independent medical review under Article 5.55 and section 1370.4 of the Act. The independent medical review process shall resolve decisions that deny, modify, or delay health care services, that deny reimbursement for urgent or emergency services or that involve experimental or investigational therapies. Specialized plans shall provide for independent medical reviews under this section if a covered service relates to the practice of medicine or is provided pursuant to a contract with a health plan providing medical, surgical and hospital services. The Department shall be the final arbiter when there is a question as to whether a dispute over a health care service is eligible for independent medical review, and whether extraordinary and compelling circumstances exist that waive the requirement that the enrollee first participate in the plan's grievance system.

(b) An enrollee may apply for an independent medical review under the conditions specified in Section 1374.30(j) of the Act. The Department may waive the requirement that the enrollee participate in the plan's grievance process if the Department determines that extraordinary and compelling circumstances exist, which include, but are 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.

(c) In cases involving a claim for out of plan emergency or urgent services that a provider determined were medically necessary, the independent medical review shall determine whether the services were emergency or urgent services necessary to screen and stabilize the enrollee's condition. For purposes of this section "emergency services" are services for emergency medical conditions as defined in section 1300.71.4 of title 28, and "urgent services" are all services, except emergency services, where the enrollee has obtained the services without prior authorization from the plan, or from a contracting provider.

(d) Applications for independent medical review shall be submitted on a one-page form entitled Independent Medical Review Application (DMHC IMR 11/00), which is incorporated by reference, and shall be provided by the Department. The form shall contain a signed release from the enrollee, or a person authorized pursuant to law to act on behalf of the enrollee, authorizing release of medical and treatment information. Additionally, the enrollee may provide any relevant material or documentation with the application including, but not limited to:

(1) A copy of the adverse determination by the plan or contracting provider notifying the enrollee that the request for health care services was denied, delayed or modified, in whole or in part, based on the determination that the service was not medically necessary;

(2) Medical records, statements from the enrollee's provider or other documents establishing that the dispute is eligible for review;

(3) A copy of the grievance requesting the health care service, or benefit filed with the plan or any entity with delegated authority to resolve grievances, and the response to the grievance, if any;

(4) If expedited review is requested for a decision eligible for independent medical review pursuant to Article 5.55 of the Act, the application shall include, a certification from the enrollee's physician or provider indicating that an imminent and serious threat to the health of the enrollee exists. If expedited review is requested for a decision eligible for independent medical review pursuant to section 1370.4 of the Act, the application shall include a certification from the enrollee's physician that the proposed therapy would be significantly less effective if not promptly initiated.

(e) If additional information is needed to complete an application or to determine the enrollee's eligibility for independent medical review, the Department shall advise the enrollee or the enrollee's representative, the enrollee's provider, the enrollee's health care plan or the enrollee's attending physician, as appropriate, by the most efficient means available.

(f) The Department shall evaluate complaints received under subsection (b) of Section 1368 of the Act and applications submitted under this regulation and determine whether the enrollee is eligible for an independent medical review. The Department's determination will consider all information provided to the Department, the enrollee's medical condition and the disputed health care service. If the Department determines that the case should not be referred to independent medical review, the request shall be considered a complaint under subsection (b) of Section 1368 and sections 1300.68 and 1300.68.01. The enrollee or the enrollee's representative, health plan and any involved provider shall be advised of the Department's determination.

(1) The request for independent medical review shall be filed with the Department within six months of the plan's written response to the enrollee's grievance. The six-month period does not begin to run until the enrollee, or the enrollee's representative, has been properly notified in writing of the plan's resolution of the grievance. Applications will not be rejected as untimely solely because the enrollee, the enrollee's provider, or the plan failed to submit supporting documentation. Requests for extensions or late applications shall be approved if a timely submission was reasonably impaired by inadequate notice of the independent medical review process or by the applicant's medical circumstances.

(2) An application will not be eligible for independent medical review if the enrollee's complaint has previously been submitted and reviewed by the Department. Exceptions may be approved if the application for independent medical review includes medical records and a statement from the enrollee's physician or provider demonstrating significant changes in the enrollee's medical condition or in medical therapies available have occurred since the Department's disposition of the complaint.

(3) Enrollees of Medi-Cal health care service plans are eligible for an independent medical review if the enrollee has not presented the disputed health care service for resolution by the

Medi-Cal fair hearing process. Reviews shall be conducted in accordance with the statutes and regulations of the Medi-Cal program.

(4) This regulation applies to Medicare enrollees, to the extent the regulation does not conflict with federal law, including 42 USCS § 1395w-26 (2004).

(g) Except for Medi-Cal enrollees, and Medicare enrollees exempted by federal law, as described at subsection (f)(4), the independent medical review system established pursuant to this section shall be the exclusive independent medical review process offered to enrollees for disputes involving the medical necessity of covered health care services. Nothing in this section shall preclude a health plan from offering other independent review processes for disputes that do not involve medical necessity.

(h) When the Department finds that a plan fails to advise an enrollee of the availability of independent medical review as required under Health and Safety Code section 1374.30(i), or engages in a practice of mischaracterizing determinations substantially based on medical necessity as coverage decisions, or otherwise interferes with the rights of enrollees to obtain independent medical review, the Department shall impose administrative penalties on the plan in accordance with the Act.

(i) The director shall notify the enrollee and the enrollee's health care plan if an application for independent medical review has been accepted within seven (7) calendar days of receipt of a completed application for a routine request and within 48 hours of receipt of a completed application for an expedited review. The notification shall identify the independent medical review organization, whether the review shall be conducted on an expedited or routine basis and other information deemed necessary by the Department. The director shall also transmit to the enrollee's health care plan a copy of the enrollee's signed release of medical and treatment information and copies of all other materials submitted with the enrollee's, application.

(j) Following receipt of the Department's notification that an application for independent medical review has been assigned to an independent medical review organization, the plan shall provide the organization with all information that was considered in relation to the disputed health care service, the enrollee's grievance and the plan's determination. The plan shall forward all information to the medical review organization within three (3) business days for a regular review and within one (1) calendar day in the case of an expedited review.

(1) Unless otherwise advised in the notification or by the assigned review organization, the plan shall submit a complete set of the materials described below for the independent review organization.

(A) A copy of all correspondence from and received by the plan concerning the disputed health care service, including but not limited to, any enrollee grievance relating to the requested service;

(B) A complete and legible copy of all medical records and other information used by the plan in making its decision regarding the disputed health care service. An additional copy of medical records shall be submitted for each reviewer.

(C) A copy of the cover page of the evidence of coverage and complete pages with the referenced sections highlighted or underlined sections, if the evidence of coverage was referenced in the plan's resolution of the enrollee's grievance;

(D) The plan's response to any additional issues raised in the enrollee's application for independent medical review.

(2) The plan shall promptly provide the enrollee with an annotated list of all documents submitted to the independent medical review organization, together with information on how copies may be requested.

(k) Plans shall be responsible for providing additional information as follows:

(1) Any medical records or other relevant matters not available at the time of the Department's initial notification, or that result from the enrollee's on-going medical care or treatment for the medical condition or disease under review. Such matters shall be forwarded as soon as possible upon receipt by the health plan, not to exceed five (5) business days in routine cases or one (1) calendar day in expedited cases.

(2) Additional medical records or other information requested by the IMR organization shall be sent within five (5) business days in routine cases or one (1) calendar day in expedited cases. In expedited reviews, the health care plan shall immediately notify the enrollee and the enrollee's health care provider by telephone or facsimile to identify and request the necessary information, followed by written notification, when the request involves materials not in the possession of the plan or its contracting providers.

(l) Each assigned reviewer shall issue a separate written analysis of the case, explaining the determination made, using plain English where possible. The analysis shall describe how the determination relates to the enrollee's medical condition and history, relevant medical records and other documents considered, and references to the specific medical and scientific evidence listed in Sections 1370.4(d) or 1374.33(b) of the Act, as applicable. For requests made pursuant to Article 5.55 of the Act, reviewers shall determine whether the disputed service is medically necessary for the enrollee. For requests made pursuant to section 1370.4 of the Act, the reviewers shall determine whether the requested therapy is likely to be more beneficial for the enrollee then other available standard therapies, and whether the plan shall provide the requested therapy. Reviews based on section 1300.70.4 of these regulations shall also reference the medical and scientific evidence considered in assessing whether the requested health care service is likely to be more beneficial than other available standard therapies. The analysis may also discuss the risks and benefits considered by the reviewer in considering proposed and standard treatments.

(m) The Department, the enrollee, or his/her representative may withdraw a case from the independent review system at any time. The plan may seek withdrawal of the case from the review system by providing the disputed health care service, subject to the concurrence of the enrollee.