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Title 28@ Managed Health Care

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Division 1@ The Department of Managed Health Care

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Chapter 2@ Health Care Service Plans

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Article 8@ Self-Policing Procedures

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Section 1300.70.4@ Independent Medical Reviews Experimental and Investigational Therapies

1300.70.4 Independent Medical Reviews Experimental and Investigational Therapies

(a)

Enrollees of a health care service plan may request an independent medical review pursuant to sections 1370.4, 1374.30 through 1374.34 of the Act and section 1300.74.30 of title 28 when the plan has denied a therapy or medical service that would otherwise be covered based on the plan's determination that the therapy or medical service is experimental or investigational. This eligibility also applies to Medicare enrollees to the extent it does not conflict with federal law.

(b)

At the time of the plan's denial of coverage for experimental or investigational therapy, or denial of urgent care or emergency services, as defined in section 1300.67(g)(2), the plan shall notify the enrollee of the ability to seek independent medical review. (1) The notification must include, at a minimum, information on the independent medical review process, an application and envelope addressed to the Department, the physician certification form and the Department's toll-free information number. (2) Pursuant to Health and Safety Code section 1368.03(a), the Department does not require that an enrollee participate in the plan's grievance system prior to seeking independent medical review.

(1)

The notification must include, at a minimum, information on the independent medical review process, an application and envelope addressed to the Department, the physician certification form and the Department's toll-free information number.

(2)

Pursuant to Health and Safety Code section 1368.03(a), the Department does not require that an enrollee participate in the plan's grievance system prior to seeking independent medical review.

(c)

Included with the enrollee's application to the Department for independent medical review shall be a copy of the plan or contracted provider's written denial of the therapy or medical service based on the determination that the therapy or service is experimental or investigational.

(d)

A certification from the enrollee's treating physician shall be included with the application for independent medical review. The physician's certification shall be on a form from the Department entitled, "Physician Certification Experimental/ Investigational Denials" (DMHC/IMR 110-11/27/00), or contain all of the following information: (1) The enrollee has a condition as defined in Health and Safety Code section 1370.4(a)(1); (2) Background information including the name of the enrollee and the health plan; the physician's name, specialty, board certification, address, telephone, and fax number; whether the physician is contracted with the plan; the enrollee's medical condition; and the specific drug, device, procedure, or other therapy recommended or requested for the enrollee's medical condition. (3) For non-contracting physicians, the certification shall also include the following: (A) The physician's license, board-certification or board eligibility to practice in the area appropriate to treat the enrollee's condition; and, (B) Reference to, or copies

of, two documents from the medical or scientific literature, specified in section 1370.4(d) of the Act. (4) The following statement and physician's signature: "I certify that the requested therapy is likely to be more beneficial than any standard therapy. The information provided herein is true and correct;" (5) Where expedited review is requested the certification shall include a statement that imminent and serious threat to the health of the enrollee exists pursuant to Health and Safety Code section 1374.31, or the proposed therapy would be significantly less effective if not promptly initiated; and (6) Attachments, including any additional references or copies of medical and/or scientific literature considered relevant to the requested therapy and any other information relevant to the request.

(1)

The enrollee has a condition as defined in Health and Safety Code section 1370.4(a)(1):

(2)

Background information including the name of the enrollee and the health plan; the physician's name, specialty, board certification, address, telephone, and fax number; whether the physician is contracted with the plan; the enrollee's medical condition; and the specific drug, device, procedure, or other therapy recommended or requested for the enrollee's medical condition.

(3)

For non-contracting physicians, the certification shall also include the following: (A) The physician's license, board-certification or board eligibility to practice in the area appropriate to treat the enrollee's condition; and, (B) Reference to, or copies of, two documents from the medical or scientific literature, specified in section 1370.4(d) of the Act.

(A)

The physician's license, board-certification or board eligibility to practice in the area appropriate to treat the enrollee's condition; and,

(B)

Reference to, or copies of, two documents from the medical or scientific literature, specified in section 1370.4(d) of the Act.

(4)

The following statement and physician's signature: "I certify that the requested therapy is likely to be more beneficial than any standard therapy. The information provided herein is true and correct;"

(5)

Where expedited review is requested the certification shall include a statement that imminent and serious threat to the health of the enrollee exists pursuant to Health and Safety Code section 1374.31, or the proposed therapy would be significantly less effective if not promptly initiated; and

(6)

Attachments, including any additional references or copies of medical and/or scientific literature considered relevant to the requested therapy and any other information relevant to the request.

(e)

Incomplete applications will not be referred to an independent medical review organization. However, the Department may waive this requirement in exceptional or compelling circumstances where the need for a prompt determination precludes obtaining all information in writing. In cases accepted for an urgent review, the enrollee's physician must certify in writing, at a minimum, that the enrollee has a life-threatening or seriously debilitating condition, as

defined in Health and Safety Code section 1370.4(a), that the requested therapy is likely to be more beneficial to the enrollee than any available standard therapy and describe the medical and scientific evidence relied upon in making the recommendation.