HOUSE BILL No. 5571

February 12, 1998, Introduced by Reps. Schroer, Wallace, Anthony, Parks, LaForge, Baade, Bogardus, Crissman, Scott, Brater, Profit, Murphy, Hale and Gire and referred to the Committee on Insurance.

A bill to create the experimental treatment dispute resolution commission; to provide for the creation of independent panels of experts; to provide for the powers and duties of the commission and the panels; to provide for certain appeals and reviews; and to require health care plans to provide certain information and follow certain recommendations.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act shall be known and may be cited as the "experimental treatment dispute resolution act".

Sec. 2. As used in this act:

(a) "Commission" means the experimental treatment dispute resolution commission created in section 5.

(b) "Enrollee" means an individual covered under a health care plan.

(c) "Health care plan" or "plan" means a medical, surgical, or health care benefit plan, contract, policy, or certificate issued under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, the nonprofit health care corporation reform act, 1980 PA 350, MCL 550.1101 to 550.1704, or the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

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

(e) "Material financial affiliation" means any financial interest of more than 5% of total annual revenue or total annual income of an entity or individual to which section 9(2) applies. Material financial affiliation does not include payment by the plan to the members of the panel for the services required by this act.

(f) "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 an entity or individual to which section 9(2) applies. Material professional affiliation does not include affiliations that are limited to staff privileges at a health facility.

(g) "Medical and scientific evidence" means the following sources:

(*i*) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally

recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(*ii*) Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the national institute of health's national library of medicine for indexing in index medicus, excerpta medicus (EMBASE), medline and MEDLARS data base health services technology assessment research (HSTAT).

(*iii*) Medical literature recognized by the secretary of health and human services, under section 1861(t)(2) of part C of title XVIII of the social security act, 42 U.S.C. 1395x.

(*iv*) The following standard reference compendia: the American hospital formulary service-drug information, the American medical association drug evaluation, the American dental association accepted dental therapeutics, and the United States pharmacopoeia-drug information.

(*v*) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognize federal research institutes including the federal agency for health care policy and research, national institutes of health, national cancer institute, national academy of sciences, health care financing administration, congressional office of technology assessment, and any national board recognized by the national institutes of health for the purpose of evaluating the medical value of health services.

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

(h) "Panel" means a panel of independent experts selected by the commission under section 9.

Sec. 5. (1) The experimental treatment dispute resolution commission is created within the department of consumer and industry services.

(2) The commission shall consist of the following members, appointed by the governor with the advice and consent of the senate:

(a) One representative of the health insurance industry in this state.

(b) One representative of the health maintenance organization industry in this state.

(c) One representative from a nonprofit health care corporation located in this state.

(d) One representative from each of the following:

(*i*) The university of Michigan medical school.

(*ii*) Wayne state university school of medicine.

(*iii*) Michigan state university college of osteopathic medicine or college of human medicine.

(e) One representative from the Michigan health and hospital association.

(f) One representative from the Michigan nurses association.

(g) One representative from the Michigan state medical society.

(h) Four representatives from the general public.

(3) The director of community health and the insurance commissioner shall be ex officio members of the commission without vote.

(4) The members first appointed to the commission shall be appointed within 30 days after the effective date of this act.

(5) Members of the commission shall serve for terms of 3 years or until a successor is appointed, whichever is later, except that of the members first appointed, 4 shall serve for 1 year, 4 shall serve for 2 years, and 5 shall serve for 3 years.

(6) If a vacancy occurs on the commission, the governor shall make an appointment for the unexpired term in the same manner as the original appointment.

(7) The governor may remove a member of the commission for incompetency, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

(8) The first meeting of the commission shall be held within 60 days after the effective date of this act. At the first meeting, the commission shall elect from among its members a chairperson and other officers as it considers necessary or appropriate. After the first meeting, the commission shall meet at least quarterly, or more frequently at the call of the chairperson or if requested by 7 or more members.

(9) A majority of the members of the commission constitute a quorum for the transaction of business at a meeting of the

commission. A majority of the members present and serving are required for official action of the commission.

(10) The business that the commission may perform shall be conducted at a public meeting of the commission held in compliance with the open meetings act, 1976 PA 267, MCL 15.261 to 15.275. However, any meeting or portion of a meeting on an individual enrollee's appeal is not subject to the open meetings act, 1976 PA 267, MCL 15.261 to 15.275.

(11) A writing prepared, owned, used, in the possession of, or retained by the commission in the performance of an official function is subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246. However, information as to an individual enrollee's appeal is exempt from the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(12) Members of the commission shall serve without compensation. However, members of the commission may be reimbursed for their actual and necessary expenses incurred in the performance of their official duties as members of the commission.

Sec. 7. (1) Upon request of an enrollee or a person authorized in writing to act on behalf of an enrollee, the commission shall appoint a panel to review a plan's coverage decision regarding experimental or investigational therapies for an enrollee who meets all of the following criteria:

(a) The enrollee has either of the following:

(*i*) A terminal condition that, according to the enrollee's physician's current diagnosis, has a high probability of causing death within 2 years from the date of the request for review.

(*ii*) A chronic condition that according to the enrollee's physician's current diagnosis reoccurs frequently and is of a duration of more than 6 months.

(b) The enrollee's physician certifies that the enrollee has a condition, as described in subdivision (a)(*i*) or (*ii*), for which standard therapies have not been effective in improving the condition of the enrollee, or for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed pursuant to subdivision (c).

(c) Either the enrollee's physician who is under contract with or employed by the plan has recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the enrollee than any available standard therapies, or the enrollee, or the enrollee's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's condition, has requested a therapy that, based on 2 medical and scientific evidence documents, is likely to be more beneficial for the enrollee than any available standard therapy. The physician certification under this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision requires the plan to pay for the services of a

nonparticipating physician that are provided pursuant to this subdivision and that are not otherwise covered under the plan.

(d) The enrollee has been denied coverage by the plan for a drug, device, procedure, or other therapy recommended or requested under subdivision (c).

(e) The specific drug, device, procedure or other therapy recommended under subdivision (c) would be a covered service, except for the plan's determination that the therapy is experimental or investigational.

(2) The plan shall provide to the commission a copy of the following documents within 5 business days of the plan's receipt of a request for an external, independent review by an enrollee or person authorized in writing to act on behalf of an enrollee:

(a) The medical records relevant to the enrollee's condition for which the proposed therapy has been recommended, provided the documents are within the plan's possession. Any medical records provided to the plan after the initial documents are provided to the panel shall be forwarded by the plan to the panel within 5 business days. The confidentiality of the medical records shall be maintained pursuant to confidentiality requirements recognized or created by law.

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

in subdivisions (a) and (c), to the enrollee and the enrollee's physician.

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

Sec. 9. (1) If the commission determines that an enrollee satisfies section 7(1), the commission shall select an independent panel of at least 3 physicians or other providers who are experts in the treatment of the enrollee's medical condition and knowledgeable about the recommended therapy. Neither the plan nor the enrollee shall choose or control the choice of the physician or other provider experts.

(2) The commission shall ensure that no member of a panel has any material professional, familial, or financial affiliation with any of the following:

(a) The plan that has denied the proposed treatment under review.

(b) Any officer, director, or management employee of the plan described in subdivision (a).

(c) The physician, the physician's medical group, or the independent practice association proposing the therapy that is under review.

(d) The institution at which the proposed therapy that is under review would be provided.

(e) The enrollee whose medical condition and the proposed treatment is under review.

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

Sec. 11. (1) The panel experts shall render their analyses and recommendations within 30 days of their appointment by the commission. If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the panel experts shall be rendered within 7 days of the request for expedited review.

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

(3) The panel experts shall provide the plan and the enrollee's physician with their analyses and recommendations, a description of the qualifications of each expert, and any other information that the panel chooses to provide to the plan and the enrollee's physician.

(4) If the majority of experts on the panel recommend providing the proposed therapy, the recommendation shall be binding on the plan and the plan shall provide coverage for the proposed therapy. If the recommendations of the experts on the panel are

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