ACT 250

S.B NO. 2655

A Bill for an Act Relating to Health.

Be It Enacted by the Legislature of the State of Hawaii:

PART I

SECTION 1. The legislature, in section 12 of Act 137, Session Laws of Hawaii 1999, directed the Hawaii patient rights and responsibilities task force to develop proposed legislation addressing issues within the scope of the task force's responsibilities under Act 178, Session Laws of Hawaii 1998. This part is submitted in response to the legislature's mandate.

SECTION 2. Chapter 432E, Hawaii Revised Statutes, is amended by adding a new section to be appropriately inserted and to read as follows:

"**§432E- Expedited appeal, when authorized; standard for decision.** (a) An enrollee may request that the following be conducted as an expedited appeal:

(1) The internal review under section 432E-5 of the enrollee's complaint; or

(2) The external review under section 432E-6 of the managed care plan's final internal determination.

If a request for expedited appeal is approved by the managed care plan or the commissioner, the appropriate review shall be completed within seventy-two hours of receipt of the request for expedited appeal.

(b) An expedited appeal shall be authorized if the application of the forty-five day standard review time frame may:

(1) Seriously jeopardize the life or health of the enrollee;

(2) Seriously jeopardize the enrollee's ability to gain maximum functioning; or

(3) Subject the enrollee to severe pain that cannot be adequately managed without the care or treatment that is the subject of the expedited appeal.

(c) The decision as to whether an enrollee's complaint is an expedited appeal shall be made by applying the standard of a reasonable individual who is not a trained health professional. The decision may be made for the managed care plan by an individual acting on behalf of the managed care plan. If a licensed health care provider with knowledge of a claimant's medical condition requests an expedited appeal on behalf of an enrollee, the request shall be treated as an expedited appeal."

Section[1] 432E-1, Hawaii Revised Statutes, is amended by adding six new definitions to be appropriately inserted and to read as follows:

"<u>"Appointed representative" means a person who is expressly permitted by the enrollee or who has the power under Hawaii law to make health care decisions on behalf of the enrollee, including:</u>

<u>(1) A court-appointed legal guardian;</u>

<u>(2) A person who has a durable power of attorney for health care; or</u>

<u>(3) A person who is designated in a written advance directive.</u>

"Expedited appeal" means the internal review of a complaint or an external review of the final internal determination of an enrollee's complaint, which is completed within seventy-two hours after receipt of the request for expedited appeal.

"External review" means an administrative review requested by an enrollee under section 432E-6 of a managed care plan's final internal determination of an enrollee's complaint.

"Health care provider" means an individual licensed or certified to provide health care in the ordinary course of business or practice of a profession.

"Independent review organization" means an independent entity that:

(1) Is unbiased and able to make independent decisions;

(2) Engages adequate numbers of practitioners with the appropriate level and type of clinical knowledge and expertise;

(3) Applies evidence-based decision making;

(4) Demonstrates an effective process to screen external reviews for eligibility;

(5) Protects the enrollee's identity from unnecessary disclosure; and

(6) Has effective systems in place to conduct a review.

"Internal review" means the review under section 432E-5 of an enrollee's complaint by a managed care plan.

"Medical necessity" means a health intervention as defined in section 432E- ."

SECTION 4[2]. Section 432E-5, Hawaii Revised Statutes, is amended to read as follows:

"**§432E-5 Complaints and appeals procedure for enrollees.** (a) A managed care plan with enrollees in this State shall establish and maintain a procedure to provide for the resolution of an enrollee's complaints and appeals. The procedure shall provide for expedited appeals under section 432E- . The definition of medical necessity in section 432E- shall apply in a managed care plan's complaints and appeals procedures.

(b) The managed care plan shall at all times [shall] make available its complaints and appeals procedures. The complaints and appeals procedures shall be reasonably understandable to the average layperson and shall be provided in [languages] a language other than English upon request.

(c) A managed care plan shall decide any expedited appeal as soon as possible after receipt of the complaint, taking into account the medical exigencies of the case, but not later than seventy-two hours after receipt of the request for expedited appeal.

[(c)] (d) A managed care plan shall send notice of its final internal determination within forty-five days of the submission of the complaint to the enrollee, the enrollee's appointed representative, if applicable, the enrollee's treating provider, and the commissioner. The notice shall include the following information regarding the enrollee's rights and procedures [under section 432E-6.]:

(1) The enrollee's right to request an external review;

(2) The sixty-day deadline for requesting the external review;

(3) Instructions on how to request an external review; and

(4) Where to submit the request for an external review."

SECTION 5[2]. Section 432E-6, Hawaii Revised Statutes, is amended to read as follows:

"**§432E-6 [Appeals to the commissioner.] External review procedure.** (a) After exhausting all internal complaint and appeal procedures available, an enrollee,

or the enrollee's treating provider or appointed representative, may [appeal an adverse decision] file a request for external review of a managed care [plan] plan's final internal determination to a three-member review panel appointed by the commissioner composed of a representative from a [health] managed care plan not involved in the complaint, a provider licensed to practice and practicing medicine in Hawaii not involved in the complaint, and the commissioner or the commissioner's designee in the following manner:

(1) The enrollee shall submit a request for external review to the commissioner within [thirty] sixty days from the date of the final internal determination by the managed care plan;

(2) The commissioner may retain:

(A) Without regard to chapters 76 and 77, an independent medical expert trained in the field of medicine most appropriately related to the matter under review. Presentation of evidence for this purpose shall be exempt from section 91-9(g); and

(B) The services of an independent review organization from an approved list maintained by the commissioner;

(3) Within seven days after receipt of the request for external review, a managed care plan or its designee utilization review organization shall provide to the commissioner or the assigned independent review organization:

(A) Any documents or information used in making the final internal determination including the enrollee's medical records;

(B) Any documentation or written information submitted to the managed care plan in support of the enrollee's initial complaint; and

(C) A list of the names, addresses, and telephone numbers of each licensed health care provider who cared for the enrollee and who may have medical records relevant to the external review;

provided that where an expedited review is involved, the managed care plan or its designee utilization review organization shall provide the documents and information within forty-eight hours of receipt of the request for external review.

Failure by the managed care plan or its designee utilization review organization to provide the documents and information within the prescribed time periods shall not delay the conduct of the external review. Where the plan or its designee utilization review organization fails to provide the documents and information within the prescribed time periods, the commissioner may issue a decision to reverse the final internal determination, in whole or part, and shall promptly notify the independent review organization, the enrollee, the enrollee's appointed representative, if applicable, the enrollee's treating provider, and the managed care plan of the decision;

[(2)] (4) Upon receipt of the request for external review and upon a showing of good cause, the commissioner shall appoint the members of the panel and shall conduct a review hearing pursuant to chapter 91. If the amount in controversy is less than $500, the commissioner may conduct a review hearing without appointing a review panel;

[(3)] (5) The review hearing shall be conducted as soon as practicable, taking into consideration the medical exigencies of the case; provided that [the]:

(A) The hearing shall be held no later than sixty days from the date of the request for the hearing; and

(B) An external review conducted as an expedited appeal shall be determined no later than seventy-two hours after receipt of the request for external review;

[(4) The commissioner may retain, without regard to chapters 76 and 77, an independent medical expert trained in the field of medicine most appropriately related to the matter under review. Presentation of evidence for this purpose shall be exempt from section 91-9(g);

(5)] (6) After considering the enrollee's complaint, the managed care plan's response, and any affidavits filed by the parties, the commissioner may dismiss the [appeal] request for external review if it is determined that the [appeal] request is frivolous or without merit; and

[(6)] (7) The review panel shall review every [adverse] final internal determination to determine whether [or not] the managed care plan involved acted reasonably [and with sound medical judgment]. The review panel and the commissioner or the commissioner's designee shall consider [the]:

(A) The terms of the agreement of the enrollee's insurance policy, evidence of coverage, or similar document;

(B) Whether the medical director properly applied the medical necessity criteria in section 432E- in making the final internal determination;

(C) All relevant medical records;

(D) The clinical standards of the plan[, the];

(E) The information provided[, the];

(F) The attending physician's recommendations[,]; and

(G) [generally] Generally accepted practice guidelines.

The commissioner, upon a majority vote of the panel, shall issue an order affirming, modifying, or reversing the decision within thirty days of the hearing.

(b) The procedure set forth in this section shall not apply to claims or allegations of health provider malpractice, professional negligence, or other professional fault against participating providers.

(c) No person shall serve on the review panel or in the independent review organization who, through a familial relationship within the second degree of consanguinity or affinity, or for other reasons, has a direct and substantial professional, financial, or personal interest in:

(1) The plan involved in the complaint, including an officer, director, or employee of the plan; or

(2) The treatment of the enrollee, including but not limited to the developer or manufacturer of the principal drug, device, procedure, or other therapy at issue.

[(c)] (d) Members of the review panel shall be granted immunity from liability and damages relating to their duties under this section.

[(d)] (e) An enrollee may be allowed, at the commissioner's discretion, an award of a reasonable sum for attorney's fees and reasonable costs [of suit in an action brought against the managed care plan.] incurred in connection with the external review under this section, unless the commissioner in an administrative proceeding determines that the appeal was unreasonable, fraudulent, excessive, or frivolous.

(f) Disclosure of an enrollee's protected health information shall be limited to disclosure for purposes relating to the external review."

SECTION 6[2]. Section 5, Act 178, Session Laws of Hawaii 1998, is amended by amending subsection (c) to read as follows:

"(c) The task force shall be [comprised] composed of interested parties with the total membership of the task force between twelve and [twenty] twenty-seven members. The insurance commissioner or the commissioner's designated representative[,] shall be a member and serve as the chair of the task force and appoint [it] its remaining members. At least one representative from each of the following shall be appointed as a member; members of other groups may also be appointed:

(1) The department of health;
(2) The department of labor and industrial relations, disability compensation division;
(3) A health insurance company that provides accident and sickness policies under chapter 431, article 10A, Hawaii Revised Statutes;
(4) A mutual benefit society that provides health insurance under chapter 432, Hawaii Revised Statutes;
(5) A health maintenance organization that holds a certificate of authority under chapter 432D, Hawaii Revised Statutes;
(6) The American Association of Retired Persons;
(7) The Hawaii Coalition for Health;
(8) The Hawai'i Business Health Coalition;
(9) The Legal Aid Society of Hawaii;
(10) The Hawaii Medical Association;
(11) An organization that represents nurses; [and]
(12) A hospital or an organization that represents hospitals[.]; and
(13) Hawaii Psychiatric Medical Association;
(14) American Academy of Pediatrics; and
(15) Family Voices."

PART II

SECTION 7[2]. In Senate Concurrent Resolution No. 152, S.D. 1, the 1999 legislature requested the Hawaii patient rights and responsibilities task force to make a thorough study of the issues relating to the use of the term "medical necessity" and determine the most appropriate definition of "medical necessity", or develop new terms to better resolve the issues examined.

The purpose of this part is to establish a statutory definition of the term "medical necessity" to:

(1) Promote uniformity among the various health plans; and
(2) Serve as the standard of review governing a health plan's internal appeals process and the external appeals process.

SECTION 8[2]. Chapter 432E, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§432E- Medical necessity.** (a) For contractual purposes, a health intervention shall be covered if it is an otherwise covered category of service, not specifically excluded, recommended by the treating licensed health care provider, and determined by the health plan's medical director to be medically necessary as defined in subsection (b). A health intervention may be medically indicated and not qualify as a covered benefit or meet the definition of medical necessity. A managed care plan may choose to cover health interventions that do not meet the definition of medical necessity.

(b) A health intervention is medically necessary if it is recommended by the treating physician or treating licensed health care provider, is approved by the health plan's medical director or physician designee, and is:

(1) For the purpose of treating a medical condition;

(2) The most appropriate delivery or level of service, considering potential benefits and harms to the patient;

(3) Known to be effective in improving health outcomes; provided that:

(A) Effectiveness is determined first by scientific evidence;

(B) If no scientific evidence exists, then by professional standards of care; and

(C) If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion;

and

(4) Cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention. For purposes of this paragraph, cost-effective shall not necessarily mean the lowest price.

(c) When the treating licensed health care provider and the health plan's medical director or physician designee do not agree on whether a health intervention is medically necessary, a reviewing body, whether internal to the plan or external, shall give consideration to, but shall not be bound by, the recommendations of the treating licensed health care provider and the health plan's medical director or physician designee.

(d) For the purposes of this section:

"Cost-effective" means a health intervention where the benefits and harms relative to the costs represent an economically efficient use of resources for patients with the medical condition being treated through the health intervention; provided that the characteristics of the individual patient shall be determinative when applying this criterion to an individual case.

"Effective" means a health intervention that may reasonably be expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.

"Health intervention" means an item or service delivered or undertaken primarily to treat a medical condition or to maintain or restore functional ability. A health intervention is defined not only by the intervention itself, but also by the medical condition and patient indications for which it is being applied. New interventions for which clinical trials have not been conducted and effectiveness has not been scientifically established shall be evaluated on the basis of professional standards of care or expert opinion. For existing interventions, scientific evidence shall be considered first and to the greatest extent possible, shall be the basis for determinations of medical necessity. If no scientific evidence is available, professional standards of care shall be considered. If professional standards of care do not exist or are outdated or contradictory, decisions about existing interventions shall be based on expert opinion. Giving priority to scientific evidence shall not mean that coverage of existing interventions shall be denied in the absence of conclusive scientific evidence. Existing interventions may meet the definition of medical necessity in the absence of scientific evidence if there is a strong conviction of effectiveness and benefit expressed through up-to-date and consistent professional standards of care, or in the absence of such standards, convincing expert opinion.

"Health outcomes" mean outcomes that affect health status as measured by the length or quality of a patient's life, primarily as perceived by the patient.

"Medical condition" means a disease, illness, injury, genetic or congenital defect, pregnancy, or a biological or psychological condition that lies outside the range of normal, age-appropriate human variation.

"Physician designee" means a physician or other health care practitioner designated to assist in the decision making process who has training and credentials at least equal to the treating licensed health care provider.

"Scientific evidence" means controlled clinical trials that either directly or indirectly demonstrate the effect of the intervention on health outcomes. If controlled clinical trials are not available, observational studies that demonstrate a causal relationship between the intervention and the health outcomes may be used. Partially controlled observational studies and uncontrolled clinical series may be suggestive, but do not by themselves demonstrate a causal relationship unless the magnitude of the effect observed exceeds anything that could be explained either by the natural history of the medical condition or potential experimental biases. Scientific evidence may be found in the following and similar sources:

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

(2) Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database Health Services Technology Assessment Research (HSTAR);

(3) Medical journals recognized by the Secretary of Health and Human Services under section 1861(t)(2) of the Social Security Act, as amended;

(4) Standard reference compendia including the American Hospital Formulary Service-Drug Information, American Medical Association Drug Evaluation, American Dental Association Accepted Dental Therapeutics, and United States Pharmacopoeia-Drug Information;

(5) Findings, studies, or research conducted by or under the auspices of federal agencies and nationally recognized federal research institutes including but not limited to the Federal Agency for Health Care Policy and Research, National Institutes for 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; and

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

"Treat" means to prevent, diagnose, detect, provide medical care, or palliate.

"Treating licensed health care provider" means a licensed health care provider who has personally evaluated the patient."

PART III

SECTION 9[2]. Statutory material to be repealed is bracketed. New statutory material is underscored.[3]

SECTION 10[2]. This Act shall take effect upon its approval.

(Approved June 19, 2000.)

Notes

1. "SECTION 3." missing.
2. Section number redesignated.
3. Edited pursuant to HRS §23G-16.5.