FIRST REGULAR SESSION

SENATE BILL NO. 165

91ST GENERAL ASSEMBLY

INTRODUCED BY SENATOR BLAND. Pre-filed December 1, 2000, and 1,000 copies ordered printed. TERRY L. SPIELER, Secretary.

AN ACT

To repeal sections 354.443 and 354.618, RSMo 2000, relating to protection of health care consumers, and to enact in lieu thereof four new sections relating to the same subject.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 354.443 and 354.618, RSMo 2000, are repealed and four new sections enacted in lieu thereof, to be known as sections 354.443, 354.616, 354.618 and 538.310, to read as follows:

354.443. 1. A health maintenance organization shall disclose to the department of insurance all financial arrangements, financial interest in, or contractual provisions with utilization review companies or any other health care provider that would encourage or limit the type, amount, duration and scope of services offered, restrict or limit referral or treatment to patients, including but not limited to financial incentives to limit, restrict or deny access to or delivery of medical or other services prior to the delivery of such services. Capitation arrangements between health maintenance organizations and health care providers shall not be considered an inducement to limit, restrict or deny access to medical services. The director shall review all financial arrangements filed with the department of insurance to determine if such arrangements offer an inducement to a provider to provide less than medically necessary services to an enrollee.

2. The capitation rate to be paid from the health maintenance organization to the health care provider is not required to be included with the financial arrangements to be filed with the department of insurance pursuant to subsection 1 of this section.

3. No health maintenance organization plan that operates a provider incentive plan shall enter into any compensation agreement with any provider of covered

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

services or pharmaceutical manufacturer pursuant to which specific payment is made directly or indirectly to the provider as an inducement or incentive to reduce or limit services, to reduce the length of stay or the use of alternative treatment settings or the use of a particular medication with respect to an individual patient.

354.616. 1. For purposes of this section, the following terms mean:

(1) "Cooperative group", a formal network of facilities that collaborate on research projects and have an established National Institutes of Health approved peer review program operating within the group. The term "cooperative group" includes the National Cancer Institute Clinical Cooperative Group, the National Cancer Institute Community Clinical Oncology Program, the AIDS Clinical Trials Group, and the Community Programs for Clinical Research in AIDS;

(2) "FDA", the federal Food and Drug Administration;

(3) "Multiple project assurance contract", a contract between an institution and the federal Department of Health and Human Services that defines the relationship of the institution to the federal Department of Health and Human Services and sets about the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects;

(4) "NIH", the National Institutes of Health;

(5) "Patient cost", the cost of medically necessary health care service that is incurred as a result of the treatment being provided to the member for purposes of the clinical trial. The term "patient cost" does not include the cost of an investigational drug or device, the cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided for purposes of the clinical trial, costs associated with managing the research associated with the clinical trial, or costs that would not be covered under the patient's policy, plan or contract for noninvestigational treatments.

2. The provisions of this section shall apply to:

(1) Insurers and nonprofit health service plans that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups on an expense-incurred basis under a health insurance policy or contract issued or delivered in the state; and

(2) Health carriers that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups under contracts that are issued or delivered in the state.

3. This section shall not apply to a policy, plan or contract paid for pursuant to Title XVIII or Title XIX of the Social Security Act.

4. A policy, plan or contract subject to this section shall provide coverage for patient cost to a member in a clinical trial as a result of treatment provided for a life-

threatening condition or prevention, early detection and treatment studies on cancer.

5. The coverage pursuant to subsection 4 of this section shall be required if:

(1) The treatment is being provided or the studies are being conducted in a Phase I, Phase II, Phase III or Phase IV clinical trial for cancer; or the treatment is being provided in a Phase II, Phase III, or Phase IV clinical trial for any other life-threatening condition;

(2) The treatment is being provided in a clinical trial approved by one of the National Institutes of Health, and NIH cooperative group or an NIH center, the FDA in the form of an investigational new drug application the federal Department of Veterans' Affairs or an institutional review board of an institution in the state which has a multiple project assurance contract approved by the Office of Protection from Research Risks of the National Institutes of Health;

(3) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise;

(4) There is no clearly superior noninvestigational treatment alternative; and

(5) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative.

6. The coverage pursuant to subsection 4 of this section may be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial for any life-threatening condition other than cancer.

7. In conjunction with the provisions of subsection 4 of this section, a policy, plan or contract shall provide coverage for patient cost incurred for drugs and devices that have been approved for sale by the FDA whether or not the FDA has approved the drug or device for use in treating the patient's particular condition to the extent that the drugs or devices are not paid for by the manufacturer, distributor or provider of that drug or device.

8. An entity seeking coverage for treatment in a clinical trial approved by the institutional review board pursuant to subdivision (2) of subsection 5 of this section shall post electronically and keep up to date a list of the clinical trials meeting the requirements of subsections 4 and 5 of this section.

354.618. 1. A health carrier shall be required to offer as an additional health plan[,] an open referral health plan whenever it markets a gatekeeper group plan as an exclusive or full replacement health plan offering to a group contract holder:

(1) In the case of group health plans offered to employers of fifty or fewer employees, the decision to accept or reject the additional open referral plan offering shall be made by the group contract holder. For health plans marketed to employers of over fifty employees, the decision to

accept or reject shall be made by the employee;

(2) Contracts currently in existence shall offer the additional open referral health plan [at the next annual renewal after August 28, 1997]; however, multiyear group contracts need not comply until the expiration of their current multiyear term unless the group contract holder elects to comply before that time;

(3) If an employer provides more than one health plan to its employees and at least one is an open referral plan, then all health benefit plans offered by such employer shall be exempt from the requirements of this section.

2. For the purposes of this act, the following terms shall mean:

(1) "Open referral plan", a plan in which the enrollee is allowed to obtain treatment for covered benefits without a referral from a primary care physician from any person licensed to provide such treatment;

(2) "Gatekeeper group plan", a plan in which the enrollee is required to obtain a referral from a primary care professional in order to access specialty care.

3. Any health benefit plan provided pursuant to the Medicaid program shall be exempt from the requirements of this section.

4. [A health carrier shall have a procedure by which a female enrollee may seek the health care services of an obstetrician/gynecologist at least once a year without first obtaining prior approval from the enrollee's primary care provider if the benefits are covered under the enrollee's health benefit plan, and the obstetrician/gynecologist is a member of the health carrier's network. In no event shall a health carrier be required to permit an enrollee to have health care

services delivered by a nonparticipating obstetrician/gynecologist. An obstetrician/gynecologist who delivers health care services directly to an enrollee shall report such visit and health care services provided to the enrollee's primary care provider. A health carrier may require an enrollee to obtain a referral from the primary care physician, if such enrollee requires more than one annual visit with an obstetrician/gynecologist.] For purposes of this subsection, a "participating obstetrician/gynecologist" shall be a provider who, under a contract with the health carrier or with its contractor or subcontractor, has agreed to provide health care services to enrollees with an expectation of receiving payment, other than coinsurance, copayments or deductibles, directly or indirectly from the health carrier.

(1) A health carrier shall allow participating obstetricians/gynecologists to be designated as primary care providers. This subsection shall not be construed to require an individual participating obstetrician/gynecologist to accept primary care provider status if the participating obstetrician/gynecologist does not wish to be designated as a primary care provider, nor to interfere with the credentialing and other selection criteria usually applied by a health carrier with respect to other providers within its network.

(2) For women not using a participating obstetrician/gynecologist as their primary care provider, no health carrier shall require as a condition to the coverage of services performed by a participating obstetrician/gynecologist that an enrollee, subscriber or insured first obtain a referral from another primary care provider, it being the intent of this subsection that a woman shall at all times have direct access to the services of a participating obstetrician/gynecologist, or both, under any health benefit plan; provided, however, that the service covered by this subsection shall be limited to those services defined by the published recommendations of the Accreditation Council for Graduate Medical Education for training as an obstetrician or gynecologist, including, but not limited to diagnosis, treatment and referral.

5. Except for good cause, a health carrier shall be prohibited either directly, or indirectly through intermediaries, from discriminating between eye care providers when selecting among providers of health services for enrollment in the network and when referring enrollees for health services provided within the scope of those professional licenses and when reimbursing amounts for covered services among persons duly licensed to provide such services. For the purposes of this section, an eye care provider may be either an optometrist licensed pursuant to chapter 336, RSMo, or a physician who specializes in opthamologic medicine, licensed pursuant to chapter 334, RSMo.

6. Nothing contained in this section shall be construed as to require a health carrier to pay for health care services not provided for in the terms of a health benefit plan.

7. Any health carrier[,] which is sponsored by a federally qualified health center and is presently in existence and which has been in existence for less than three years shall be exempt from this section for a period not to exceed two years from August 28, 1997.

8. A health carrier shall not be required to offer the direct access rider for a group contract holder's health benefit plan if the health benefit plan is being provided pursuant to the terms of a collective bargaining agreement with a labor union, in accordance with federal law and the labor union has declined such option on behalf of its members.

9. Nothing in this act shall be construed to preempt the employer's right to select the health care provider pursuant to section 287.140, RSMo, in a case where an employee incurs a work-related injury covered by the provisions of chapter 287, RSMo.

10. Nothing contained in this act shall apply to certified managed care organizations while providing medical treatment to injured employees entitled to receive health benefits under chapter 287, RSMo, pursuant to contractual arrangements with employers, or their insurers, [under] **pursuant to** section 287.135, RSMo.

538.310. 1. As used in this section, unless the context otherwise requires, the following terms shall mean:

(1) "Appropriate and medically necessary", the standard for health care services

as determined by physicians and health care providers in accordance with the prevailing practices and standards of the medical profession and community;

(2) "Enrollee", a policyholder, subscriber, covered person or other individual participating in a health benefit plan;

(3) "Health care treatment decision", a determination as to the nature, extent or quality of medical care, diagnosis or treatment to be rendered to the enrollee, other than whether the medical care, diagnosis or treatment requested, recommended or approved is a covered benefit under the terms of the health maintenance organization plan;

(4) "Health maintenance organization", any person which undertakes to provide or arrange for basic and supplemental health care services to enrollees on a prepaid basis, or which meets the requirements of section 1301 of the United States Public Health Service Act;

(5) "Health maintenance organization plan", any arrangement whereby any person undertakes to provide, arrange for, pay for or reimburse any part of the cost of any health care services and at least part of such arrangement consists of providing and assuring the availability of basic health care services to enrollees, as distinguished from mere indemnification against the cost of such services, on a prepaid basis through insurance or otherwise, and as distinguished from the mere provision of service benefits under health service corporation programs;

(6) "Ordinary care", in the case of a health maintenance organization, that degree of care that a health maintenance organization of ordinary prudence would use under the same or similar circumstances. In the case of a person who is an employee, agent, ostensible agent or representative of a health maintenance organization, "ordinary care" is that degree of care that a person of ordinary prudence in the same profession, speciality or area of practice as such person would use in the same or similar circumstances;

(7) "Provider", any physician, hospital or other person which is licensed or otherwise authorized in this state to furnish health care services that has entered into an agreement with a health maintenance organization to provide such services or supplies to persons enrolled in a health maintenance organization plan.

2. Notwithstanding any other provision of law to the contrary, a health maintenance organization has the duty to exercise ordinary care when making health care treatment decisions and is liable for damages for harm to an enrollee proximately caused by its failure to exercise such ordinary care.

3. A health maintenance organization is also liable for damages for harm to an enrollee proximately caused by the health care treatment decisions made by its:

- (1) Employees;
- (2) Agents;

(3) Ostensible agents; or

(4) Representatives who are acting on its behalf and over whom it has the right to exercise influence or control or has actually exercised influence or control when those decisions result in the failure to exercise ordinary care.

4. It shall be a defense to any action asserted against a health maintenance organization that:

(1) Neither the health maintenance organization, nor any employee, agent, ostensible agent or representative for whose conduct such health maintenance organization is liable pursuant to subsection 3 of this section, controlled, influenced or participated in the health care treatment decision; and

(2) The health maintenance organization did not deny or delay payment for any treatment prescribed or recommended by a provider to the enrollee.

5. The standards in subsections 2 and 3 of this section shall not create obligation on the part of the health maintenance organization to provide to an enrollee treatment which is not covered by the health maintenance organization plan.

6. This section shall not apply to workers' compensation insurance coverage as provided by chapter 287, RSMo.

7. This section shall not create any liability on the part of an employer or an employer group purchasing organization that purchases coverage or assumes risk on behalf of its employees.

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