FIRST REGULAR SESSION

SENATE BILL NO. 86

92ND GENERAL ASSEMBLY

INTRODUCED BY SENATOR DOUGHERTY.

Pre-filed December 1, 2002, and 1,000 copies ordered printed.

TERRY L. SPIELER, Secretary.

0446S.01I

AN ACT

To repeal sections 194.220, 376.429, and 376.1250, RSMo, and to enact in lieu thereof three new sections relating to health care.

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

Section A. Sections 194.220, 376.429, and 376.1250, RSMo, are repealed and three new sections enacted in lieu thereof, to be known as sections 194.220, 376.429, and 376.1250, to read as follows:

194.220. 1. Any individual of sound mind who is at least eighteen years of age may give all or any part of his or her body for any purpose specified in section 194.230, the gift to take effect upon death. Any individual who is a minor and at least sixteen years of age may effectuate a gift for any purpose specified in section 194.230, provided parental or guardian consent is deemed given. Parental or guardian consent shall be noted on the minor's donor card, **[**application for the**]** donor's instruction permit or driver's license, or other document of gift. An express gift that is not revoked by the donor before death is irrevocable, and the donee shall be authorized to accept the gift without obtaining the consent of any other person. The provisions of this subsection, relating to allowing a minor who is at least sixteen years of age to effectuate a gift for any purpose specified in section 194.230, through the driver's license or instruction permit application process, shall be effective July 1, 2003.

2. Any of the following persons, in order of priority stated, when persons in prior classes are not available at the time of death, and in the absence of actual knowledge of a gift by the decedent pursuant to subsection 1 of this section or actual notice of contrary indications by the decedent or of opposition by a member of the same or a prior class, may give all or any part of

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

the decedent's body for any purpose specified in section 194.230:

(1) An attorney-in-fact under a durable power of attorney that expressly refers to making a gift of all or part of the principal's body pursuant to the uniform anatomical gift act;

(2) The spouse;

(3) An adult son or daughter;

(4) Either parent;

(5) An adult brother or sister;

(6) A guardian of the person of the decedent at the time of his or her death;

(7) Any other person authorized or under obligation to dispose of the body.

3. If the donee has actual notice of contrary indications by the decedent or that a gift by a member of a class is opposed by a member of the same or a prior class, the donee shall not accept the gift. The persons authorized by subsection 2 of this section may make the gift after or immediately before death.

4. A gift of all or part of a body authorizes any examination necessary to assure medical acceptability of the gift for the purposes intended.

5. The rights of the donee created by the gift are paramount to the rights of others except as provided by subsection 4 of section 194.270.

376.429. 1. All health benefit plans, as defined in section 376.1350, that are delivered, issued for delivery, continued or renewed on or after August 28, 2002, and providing coverage to any resident of this state shall provide coverage for routine patient care costs as defined in subsection 6 of this section incurred as the result of phase **I, II,** III**,** or IV of a clinical trial that is approved by an entity listed in subsection 4 of this section and is undertaken for the purposes of the prevention, early detection, or treatment of cancer.

2. In the case of treatment under a clinical trial, the treating facility and personnel must have the expertise and training to provide the treatment and treat a sufficient volume of patients. There must be equal to or superior, noninvestigational treatment alternatives and the available clinical or preclinical data must provide a reasonable expectation that the treatment will be superior to the noninvestigational alternatives.

3. Coverage required by this section shall include coverage for routine patient care costs incurred for drugs and devices that have been approved for sale by the Food and Drug Administration (FDA), regardless of whether approved by the FDA for use in treating the patient's particular condition, including coverage for reasonable and medically necessary services needed to administer the drug or use the device under evaluation in the clinical trial.

4. Subsections 1 and 2 of this section requiring coverage for routine patient care costs shall apply to clinical trials that are approved or funded by one of the following entities:

(1) One of the National Institutes of Health (NIH);

(2) An NIH cooperative group or center as defined in subsection 6 of this section;

(3) The FDA in the form of an investigational new drug application;

(4) The federal Departments of Veterans' Affairs or Defense;

(5) An institutional review board in this state that has an appropriate assurance approved by the Department of Health and Human Services assuring compliance with and implementation of regulations for the protection of human subjects (45 CFR 46); or

(6) A qualified research entity that meets the criteria for NIH Center support grant eligibility.

5. An entity seeking coverage for treatment, prevention, or early detection in a clinical trial approved by an institutional review board under subdivision (5) of subsection 4 of this section shall maintain and post electronically a list of the clinical trials meeting the requirements of subsections 2 and 3 of this section. This list shall include: the phase for which the clinical trial is approved; the entity approving the trial; **[**whether the trial is for the treatment of cancer or other serious or life-threatening disease, and if not cancer, the particular disease;**]** and the number of participants in the trial. If the electronic posting is not practical, the entity seeking coverage shall periodically provide payers and providers in the state with a written list of trials providing the information required in this section.

6. As used in this section, the following terms shall mean:

(1) "Cooperative group", a formal network of facilities that collaborate on research projects and have an established NIH-approved Peer Review Program operating within the group, including the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program;

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

(3) "Routine patient care costs", shall include coverage for reasonable and medically necessary services needed to administer the drug or device under evaluation in the clinical trial. Routine patient care costs include all items and services that are otherwise generally available to a qualified individual that are provided in the clinical trial except:

(a) The investigational item or service itself;

(b) Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and

(c) Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

7. For the purpose of this section, providers participating in clinical trials shall obtain a patient's informed consent for participation on the clinical trial in a manner that is consistent with current legal and ethical standards. Such documents shall be made available to the health

insurer upon request.

8. The provisions of this section shall not apply to a policy, plan or contract paid under Title XVIII or Title XIX of the Social Security Act.

9. Nothing in this section shall apply to accident-only, specified disease, hospital indemnity, Medicare supplement, long-term care, or other limited benefit health insurance policies.

376.1250. 1. All individual and group health insurance policies providing coverage on an expense-incurred basis, individual and group service or indemnity type contracts issued by a nonprofit corporation, individual and group service contracts issued by a health maintenance organization, all self-insured group arrangements to the extent not preempted by federal law and all managed health care delivery entities of any type or description, that are delivered, issued for delivery, continued or renewed on or after August 28, 1999, and providing coverage to any resident of this state shall provide benefits or coverage for:

(1) A pelvic examination and Pap smear for any nonsymptomatic woman covered under such policy or contract, in accordance with the current American Cancer Society guidelines;

(2) A prostate examination and laboratory tests for cancer for any nonsymptomatic man covered under such policy or contract, in accordance with the current American Cancer Society guidelines**. Such benefits and coverage shall include bone scans and prostate antibody imaging for any otherwise nonsymptomatic man covered under such policy or contract for which there is an earlier diagnosis or for reoccurrence, and as a guide for appropriate therapy in patients who have an above normal prostate specific antigen (PSA)**; and

(3) A colorectal cancer examination and laboratory tests for cancer for any nonsymptomatic person covered under such policy or contract, in accordance with the current American Cancer Society guidelines.

2. Coverage and benefits related to the examinations and tests as required by this section shall be at least as favorable and subject to the same dollar limits, deductible, and co-payments as other covered benefits or services.

3. Nothing in this act shall apply to accident-only, hospital indemnity, Medicare supplement, long-term care, or other limited benefit health insurance policies.

4. The provisions of this section shall not apply to short-term major medical policies of six months or less duration.

5. The attending physician shall make available to any patient the advantages, disadvantages, and risks, including cancer, associated with breast implantation prior to such operation as provided by the department of health and senior services.

6. The department of health and senior services shall:

(1) Make available a standardized written summary that would be clear to a prudent lay

person that:

(a) Contains general information on breast implantation; and

(b) Discloses potential dangers and side effects of a breast implantation operation;

(2) Update the standardized written summary as deemed necessary by the department of health and senior services; and

(3) By January 1, 2000, the department shall make available the standardized written summary to all hospitals, clinics, and physicians' offices that perform breast implantation.

7. The attending physician satisfies the requirements of subsection 5 of this section if:

(1) The physician provides the breast implantation patient with the standardized written summary described in subsection 2 of this section;

(2) The patient receives the standardized written summary at least five days before the breast implantation operation; and

(3) The patient signs a statement, made available by the department of health and senior services, acknowledging the patient's receipt of the standardized written summary.

8. Failure of the department of health and senior services to make the summary available, as described in subsection 6 of this section, shall be an affirmative defense in an action alleging a violation of subsection 5 of this section for the attending physician.

9. Nothing in this section shall alter, impair or otherwise affect claims, rights or remedies available pursuant to law.