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By: **Delegate Krysiak**
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CHAPTER_____

AN ACT concerning

Health Insurance - Medical Clinical Trials - Coverage

FOR the purpose of requiring certain insurers, nonprofit health service plans, and health maintenance organizations to provide coverage under certain circumstances for certain patient cost incurred as a result of treatment being provided in a Phase I clinical trial for a life-threatening condition other than cancer; providing for the application of this Act; and generally relating to coverage for patient cost incurred as a result of a treatment being provided in accordance with a clinical trial.

BY repealing and reenacting, with amendments,
Article - Insurance
Section 15-827
Annotated Code of Maryland
(1997 Volume and 1998 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Insurance

15-827.

(a) (1) In this section the following words have the meanings indicated.

(2) (i) "Cooperative group" means a formal network of facilities that collaborate on research projects and have an established NIH-approved Peer Review Program operating within the group.

(ii) "Cooperative group" includes:

1. the National Cancer Institute Clinical Cooperative Group;

2. the National Cancer Institute Community Clinical Oncology Program;

3. the AIDS Clinical Trials Group; and

4. the Community Programs for Clinical Research in AIDS.

(3) "FDA" means the federal Food and Drug Administration.

(4) "Member" means a policyholder, subscriber, insured, or certificate holder or a covered dependent of a policyholder, subscriber, insured, or certificate holder.

(5) "Multiple project assurance contract" means 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 out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

(6) "NIH" means the National Institutes of Health.

(7) (i) "Patient cost" means the cost of a 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.

(ii) "Patient cost" does not include:

1. the cost of an investigational drug or device;

2. 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;

3. costs associated with managing the research associated with the clinical trial; or

4. costs that would not be covered under the patient's policy, plan, or contract for noninvestigational treatments.

(b) This section applies 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 maintenance organizations that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups under contracts that are issued or delivered in the State.

(c) This section does not apply to a policy, plan, or contract paid for under Title XVIII or Title XIX of the Social Security Act.

(d) 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:

(1) treatment provided for a life-threatening condition; or

(2) prevention, early detection, and treatment studies on cancer.

(e) The coverage under subsection (d) of this section shall be required if:

(1) (i) 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

(ii) the treatment is being provided in a PHASE I, 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:

(i) one of the National Institutes of Health;

(ii) an NIH cooperative group or an NIH center;

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

(iv) the federal Department of Veterans Affairs; or

(v) 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 Institutions 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.

[(f) The coverage under subsection (d) 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.]

[(g)] (F) In conjunction with the provisions of subsection (d) 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.

[(h)] (G) (1) An entity seeking coverage for treatment in a clinical trial approved by an institutional review board under subsection (e)(2)(v) of this section shall post electronically and keep up-to-date a list of the clinical trials meeting the requirements of subsections (d) and (e) of this section.

(2) The list shall include, for each clinical trial:

(i) the phase for which the trial is approved;

(ii) the entity approving the trial;

(iii) whether the trial is for treatment of cancer or another life-threatening disease and, if not cancer, the particular disease; and

(iv) the estimated number of participants in the trial.

[(i)] (H) This section may not be construed to affect compliance with § 15-804 of this subtitle regarding coverage for off-label use of drugs.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all new policies, contracts, or health benefit plans issued or delivered in the State on or after July 1, 1999, and to the renewal of all policies, contracts, or health benefit plans in effect before that date, except that any policy, contract, or health benefit plan in effect before July 1, 1999, shall comply with the provisions of this Act no later than January 1, 2000.

SECTION 3. AND BE IT FURTHER ENACTED, That, subject to Section 2 of this Act, this Act shall take effect July 1, 1999.