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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 647 Session of 2001

INTRODUCED BY DeLUCA, BEBKO-JONES, BELARDI, BELFANTI, BISHOP, CAPPABIANCA, M. COHEN, CORRIGAN, COSTA, CURRY, FRANKEL, FREEMAN, GEORGE, HARHAI, HENNESSEY, JAMES, JOSEPHS, LAUGHLIN, MANDERINO, MICHLOVIC, OLIVER, ORIE, PISTELLA, READSHAW, SCRIMENTI, SOLOBAY, STABACK, STEELMAN, STURLA, SURRA, TIGUE, TRAVAGLIO, TRELLO, TRICH, VEON, WALKO, C. WILLIAMS, WOJNAROSKI, YEWCIC AND YOUNGBLOOD, FEBRUARY 12, 2001

REFERRED TO COMMITTEE ON INSURANCE, FEBRUARY 12, 2001

AN ACT

Amending the act of May 17, 1921 (P.L.682, No.284), entitled "An act relating to insurance; amending, revising, and consolidating the law providing for the incorporation of insurance companies, and the regulation, supervision, and protection of home and foreign insurance companies, Lloyds associations, reciprocal and inter-insurance exchanges, and fire insurance rating bureaus, and the regulation and supervision of insurance carried by such companies, associations, and exchanges, including insurance carried by the State Workmen's Insurance Fund; providing penalties; and repealing existing laws," providing for health insurance coverage for cancer clinical trials costs.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921, is amended by adding a section to read:

Section 631.1. Reimbursement for Clinical Trials.--(a) Any other provision of law notwithstanding, any individual or group health, sickness and accident insurance policy, group health

insurance plans/policies, and all other forms of managed/capitated care plans/policies or subscriber contract or certificate issued by any entity subject to 40 Pa.C.S. Ch. 61 (relating to hospital plan corporations) or 63 (relating to professional health services plan corporations) or the act of December 29, 1972 (P.L.1701, No.364), known as the "Health Maintenance Organization Act," the act of December 14, 1992 (P.L.835, No.134), known as the "Fraternal Benefit Societies Code," or this act providing hospital or medical/surgical coverage shall provide coverage for patient costs incurred during participation in clinical trials for treatment studies on cancer, including ovarian cancer trials, under any such policy, contract or plan delivered, issued for delivery, or renewed in this Commonwealth on and after July 1, 1999. The benefits specified in this section may be provided through a combination of policies, contracts, certificates or riders, including major medical contracts.

(b) The reimbursement for patient costs incurred during participation in clinical trials for treatment studies on cancer shall be determined in the same manner as reimbursement is determined for other medical and surgical procedures. Such coverage shall have durational limits, dollar limits, deductibles, copayments and coinsurance factors that are no less favorable than for physical illness generally.

(c) Coverage for patient costs incurred during clinical trials for treatment studies on cancer shall be provided if the treatment is being conducted in a Phase II, Phase III or Phase IV clinical trial. Such treatment may, however, be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial.

(d) The treatment described in subsection (c) shall be provided by a clinical trial approved by one of the following:

(1) The National Cancer Institute.

(2) An NCI cooperative group or an NCI center.

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

(4) The United States Department of Veterans Affairs.

(5) An institutional review board of an institution in this Commonwealth that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NCI.

(e) The facility and personnel providing the treatment shall be capable of doing so by virtue of their experience, training and expertise.

(f) Coverage under this section shall apply only if:

(1) There is no clearly superior, noninvestigational treatment alternative.

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

(3) The member and the physician or health care provider who provides services to the member under the insurance policy, subscriber contract or health care plan conclude that the member's participation in the clinical trial would be appropriate, pursuant to procedures established by the insurer, corporation or health maintenance organization and as disclosed in the policy and evidence of coverage.

(g) This section shall not apply to short-term travel, accident-only, limited or specified disease policies or contracts designed for issuance to persons eligible for coverage

under Title XVIII of the Social Security Act (49 Stat. 620, 42 U.S.C. § 301 et seq.), known as Medicare, or any other similar coverage under State or governmental plans or to short-term nonrenewable policies of not more than six months' duration.

(h) Definitions.--As used in this section, the following words and phrases shall have the meanings given to them in this subsection:

(1) "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. The term includes:

(i) The National Cancer Institute Clinical Cooperative Group.

(ii) The National Cancer Institute Community Clinical Oncology Program.

(2) "FDA" means the United States Food and Drug Administration.

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

(4) "Multiple project assurance contract" means a contract between an institution and the Department of Health and Human Services (DHHS) (20 U.S.C. § 3508) that defines the relationship of the institution to the 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.

(5) "NCI" means the National Cancer Institute.

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

(7) "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 a clinical trial. The term does not include:

(i) 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 a clinical trial.

(ii) Costs associated with managing the research associated with the clinical trial.

(iii) The cost of the investigational drug or device.

Section 2. This act shall take effect immediately.