PRIOR PRINTER'S NO. 77 PRINTER'S NO. 949

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 85 Session of 2009

INTRODUCED BY DeLUCA, HORNAMAN, BARRAR, BELFANTI, BRENNAN, BUXTON, CALTAGIRONE, CREIGHTON, DONATUCCI, EVERETT, FABRIZIO, FRANKEL, GEORGE, GERGELY, GIBBONS, GOODMAN, GRELL, HARKINS, KORTZ, KOTIK, LEVDANSKY, MAHONEY, McCALL, McGEEHAN, McILVAINE SMITH, MELIO, MUNDY, D. O'BRIEN, M. O'BRIEN, READSHAW, REICHLEY, SABATINA, SAYLOR, SCAVELLO, SIPTROTH, SONNEY, STABACK, STERN, VULAKOVICH, WALKO, WHITE, WANSACZ, HARPER, HALUSKA, K. SMITH, GERBER, GINGRICH, MURT, MYERS, BARBIN AND ROEBUCK, JANUARY 28, 2009

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, MARCH 11, 2009

AN ACT

Providing for insurance coverage for patient costs associated with cancer clinical trials.

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

Section 1. Short title.

This act shall be known and may be cited as the Cancer Clinical Trials Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Carrier." An insurance company, health service corporation, hospital service corporation, medical service corporation or health maintenance organization authorized to issue health

benefits plans in this Commonwealth.

"Cooperative group." A formal network of facilities that collaborates on research projects and that has an established National Institutes of Health approved peer review program operating within the group, including the National Cancer Institute clinical cooperative group and the National Cancer Institute community clinical oncology program.

"Health benefits plan." A hospital and medical expense insurance policy or certificate; health, hospital or medical service corporation contract or certificate; or health maintenance organization subscriber contract or certificate delivered or issued for delivery in this Commonwealth by any carrier. The term excludes the following plans, policies or contracts: specified disease, CHAMPUS supplement, accident only, credit, disability, long-term care, coverage for Medicare services pursuant to a contract with the Federal Government, Medicare supplement, dental only or vision only, insurance issued as a supplement to liability insurance, coverage arising out of a workers' compensation or similar law, hospital confinement or other supplemental limited benefit insurance coverage or automobile medical payment insurance.

"Institutional review board." Any board, committee or other group that is both:

(1) Formally designated by an institution to approve the initiation of and to conduct periodic review of biomedical research involving human subjects and in which the primary purpose of such review is to assure the protection of the rights and welfare of the human subjects and not to review a clinical trial for scientific merit.

(2) Approved by the National Institutes of Health office

for protection from research risks.

"Multiple project assurance contract." A contract between an institution and the United States Department of Health and Human Services that defines the relationship of the institution to the United States Department of Health and Human Services and that sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

"Patient." The subscriber, insured or enrollee or the covered dependent of the subscriber, insured or enrollee.

~~"Patient cost." Any fee or expense that is covered under the policy, contract or certificate and that is for a service or treatment that would be required if the patient were receiving usual and customary care. The term does not include the cost:~~

~~(1) Of any drug or device provided in a Phase I cancer clinical trial.~~

~~(2) Of any investigational drug or device.~~

~~(3) Of nonhealth services that might be required for a person to receive treatment or intervention.~~

~~(4) Of managing the research of the clinical trial.~~

~~(5) That would not be covered under the patient's contract.~~

~~(6) Of treatment or services provided outside this Commonwealth.~~

"ROUTINE CARE COSTS." PHYSICIAN FEES, LABORATORY EXPENSES AND EXPENSES ASSOCIATED WITH THE HOSPITALIZATION, ADMINISTERING OF TREATMENT AND EVALUATION OF THE PATIENT DURING THE COURSE OF TREATMENT WHICH ARE CONSISTENT WITH USUAL AND CUSTOMARY PATTERNS AND STANDARDS OF CARE INCURRED WHENEVER AN ENROLLEE, SUBSCRIBER OR INSURED RECEIVES MEDICAL CARE ASSOCIATED WITH AN APPROVED

CANCER CLINICAL TRIAL AND WHICH WOULD BE COVERED IF SUCH ITEMS AND SERVICES WERE PROVIDED OTHER THAN IN CONNECTION WITH AN APPROVED CANCER CLINICAL TRIAL.

Section 3. Coverage for clinical cancer trials.

(a) General rule.--A carrier is not obligated to pay any costs, other than ~~covered patient~~ ROUTINE CARE costs, that are directly associated with a cancer clinical trial that is offered in this Commonwealth and in which the subscriber, insured or enrollee participates voluntarily. A cancer clinical trial is a course of treatment in which all of the following apply:

(1) The treatment is part of a scientific study of a new therapy or intervention that is being conducted at an institution in this Commonwealth, that is for the treatment, palliation or prevention of cancer in humans and in which the scientific study includes all of the following:

(i) Specific goals.

(ii) A rationale and background for the study.

(iii) Criteria for patient selection.

(iv) Specific directions for administering the therapy and monitoring patients.

(v) A definition of quantitative measures for determining treatment response.

(vi) Methods for documenting and treating adverse reactions.

(2) The treatment is being provided as part of a study being conducted in a Phase I, Phase II, Phase III or Phase IV cancer clinical trial.

(3) The treatment is being provided as part of a study being conducted in accordance with a clinical trial approved by at least one of the following:

(i) One of the National Institutes of Health.

(ii) A National Institutes of Health cooperative group or center.

(iii) The United States Food and Drug Administration in the form of an investigational new drug application.

(iv) The United States Department of Defense.

(v) The United States Department of Veterans Affairs.

(vi) A qualified research entity that meets the criteria established by the National Institutes of Health for grant eligibility.

(vii) A panel of qualified recognized experts in clinical research within academic health institutions in this Commonwealth.

(4) The proposed treatment or study has been reviewed and approved by an institutional review board of an institution in this Commonwealth.

(5) The personnel providing the treatment or conducting the study:

(i) Are providing the treatment or conducting the study within their scope of practice, experience and training and are capable of providing the treatment because of their experience, training and volume of patients treated to maintain expertise.

(ii) Agree to accept reimbursement as payment in full from the carrier at the rates that are established by the carrier and that are not more than the level of reimbursement applicable to other similar services provided by health care providers with the carrier's provider network.

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

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

(b) Liability.--Pursuant to the patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of a cancer clinical trial.

(c) Benefits.--Each health benefits plan delivered or issued for delivery in this Commonwealth shall provide benefits under the plan, and those benefits shall not supplant any portion of the clinical trial that is customarily paid for by government, biotechnical, pharmaceutical or medical device industry sources.

(d) Remedy.--This section does not create any private right or cause of action for or on behalf of any patient against the carrier. This section provides solely an administrative remedy for any violation of this section or any related rule.

(e) Deductibles and other cost sharing.--Nothing in this section prohibits the carrier from imposing deductibles, coinsurance or other cost sharing measures in relation to benefits provided pursuant to this section.

~~(f) Trade association participation.--A trade association that represents a carrier may select a representative to voluntarily serve on the institutional review board of an institution in this Commonwealth that reviews and approves the proposed treatment or study conducted during the cancer clinical trial.~~

Section 4. Applicability.

This act applies to health benefit plans issued or renewed on or after January 1, 2010.

Section 5. Effective date.

This act shall take effect immediately.