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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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HOUSE BILL

No. 230 Session of  
2013

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INTRODUCED BY DELUCA, C. HARRIS, STURLA, B. BOYLE, O'BRIEN, D.  
COSTA, HESS, BROWNLEE, HARHAI, FABRIZIO, FLECK, KORTZ,  
BENNINGHOFF, MCCARTER, READSHAW, BOBACK, MATZIE AND FREEMAN,  
JANUARY 22, 2013

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REFERRED TO COMMITTEE ON INSURANCE, JANUARY 22, 2013

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AN ACT

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

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

5 Section 1. Short title.

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

8 Section 2. Definitions.

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

12 "Carrier." An insurance company, health service corporation,  
13 hospital service corporation, medical service corporation or  
14 health maintenance organization authorized to issue health  
15 benefits plans in this Commonwealth.

16 "Cooperative group." A formal network of facilities that  
17 collaborates on research projects and that has an established

1 National Institutes of Health approved peer review program  
2 operating within the group, including the National Cancer  
3 Institute clinical cooperative group and the National Cancer  
4 Institute community clinical oncology program.

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

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

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

27 (2) Approved by the National Institutes of Health office  
28 for protection from research risks.

29 "Multiple project assurance contract." A contract between an  
30 institution and the United States Department of Health and Human

1 Services that defines the relationship of the institution to the  
2 United States Department of Health and Human Services and that  
3 sets out the responsibilities of the institution and the  
4 procedures that will be used by the institution to protect human  
5 subjects.

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

8 "Routine care costs." Physician fees, laboratory expenses  
9 and expenses associated with the hospitalization, administering  
10 of treatment and evaluation of the patient during the course of  
11 treatment which are consistent with usual and customary patterns  
12 and standards of care incurred whenever an enrollee, subscriber  
13 or insured receives medical care associated with an approved  
14 cancer clinical trial and which would be covered if such items  
15 and services were provided other than in connection with an  
16 approved cancer clinical trial.

17 Section 3. Coverage for clinical cancer trials.

18 (a) General rule.--A carrier is not obligated to pay any  
19 costs, other than routine care costs, that are directly  
20 associated with a cancer clinical trial that is offered in this  
21 Commonwealth and in which the subscriber, insured or enrollee  
22 participates voluntarily. A cancer clinical trial is a course of  
23 treatment in which all of the following apply:

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

29 (i) Specific goals.

30 (ii) A rationale and background for the study.

- 1 (iii) Criteria for patient selection.
- 2 (iv) Specific directions for administering the  
3 therapy and monitoring patients.
- 4 (v) A definition of quantitative measures for  
5 determining treatment response.
- 6 (vi) Methods for documenting and treating adverse  
7 reactions.
- 8 (2) The treatment is being provided as part of a study  
9 being conducted in a Phase I, Phase II, Phase III or Phase IV  
10 cancer clinical trial.
- 11 (3) The treatment is being provided as part of a study  
12 being conducted in accordance with a clinical trial approved  
13 by at least one of the following:
- 14 (i) One of the National Institutes of Health.
- 15 (ii) A National Institutes of Health cooperative  
16 group or center.
- 17 (iii) The United States Food and Drug Administration  
18 in the form of an investigational new drug application.
- 19 (iv) The United States Department of Defense.
- 20 (v) The United States Department of Veterans  
21 Affairs.
- 22 (vi) A qualified research entity that meets the  
23 criteria established by the National Institutes of Health  
24 for grant eligibility.
- 25 (vii) A panel of qualified recognized experts in  
26 clinical research within academic health institutions in  
27 this Commonwealth.
- 28 (4) The proposed treatment or study has been reviewed  
29 and approved by an institutional review board of an  
30 institution in this Commonwealth.

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

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

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

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

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

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

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

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

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

5 Section 4. Applicability.

6 This act applies to health benefit plans issued or renewed on  
7 or after January 1, 2014.

8 Section 5. Effective date.

9 This act shall take effect immediately.