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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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**HOUSE BILL**  
**No. 3074** Session of  
2006

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INTRODUCED BY PERZEL, ALLEN, BALDWIN, BARRAR, BEYER, BLAUM,  
BUNT, BUXTON, CALTAGIRONE, CAPPELLI, COHEN, CORNELL, COSTA,  
DeWEESE, DIVEN, GEIST, GOODMAN, GRUCELA, HARHART, HENNESSEY,  
HERSHEY, HESS, JAMES, W. KELLER, KENNEY, KOTIK, LEACH,  
MARKOSEK, MARSICO, MCGILL, MCILHATTAN, MICOZZIE, S. MILLER,  
MUSTIO, PAYNE, PHILLIPS, PICKETT, PISTELLA, PYLE, RAYMOND,  
SABATINA, SAINATO, SANTONI, SATHER, SHAPIRO, SONNEY,  
E. Z. TAYLOR, TIGUE, TRUE, WALKO, WATSON, WOJNAROSKI AND ZUG,  
OCTOBER 24, 2006

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REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES,  
OCTOBER 24, 2006

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AN ACT

1 Providing for insurance coverage for routine patient care costs  
2 when an insured, enrollee or subscriber participates in  
3 approved cancer clinical trials; establishing the  
4 Pennsylvania Cancer Clinical Trial Review Board to adjudicate  
5 disputes involving third-party reimbursement for routine  
6 patient care costs incurred in association with approved  
7 cancer clinical trials; and providing for hearings and  
8 appeals.

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

11 Section 1. Short title.

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

14 Section 2. Statement of purpose.

15 It is the policy of the General Assembly and the intent and  
16 purpose of this act that the routine patient care expenses of  
17 approved cancer clinical trials be paid or reimbursed by

1 insurers and other health care providers to promote the health  
2 and welfare of the people of this Commonwealth. Sound health  
3 care practices such as approved cancer clinical trials which  
4 meet the requirements of this act should be available to all of  
5 the residents of this Commonwealth notwithstanding the practices  
6 and the discretion of insurers and other health care providers.  
7 Scientists believe that higher participation in cancer clinical  
8 trials will lead to faster development of therapies for those in  
9 need. For decades well over 50% of pediatric cancer patients  
10 were enrolled in clinical trials, and today, 75% of cancers in  
11 children are curable. In 2000, about 600 cancer clinical trials  
12 were in progress, but only 45,000 cancer patients were enrolled.  
13 If more health care providers covered these trials, more people  
14 would participate. Coverage for clinical trials would lead to  
15 new therapies and treatments as well as help cancer patients in  
16 this Commonwealth.

17 Section 3. Definitions.

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

21 "Approved cancer clinical trial." A scientific study of a  
22 new therapy for the treatment of cancer in human beings that  
23 meets the requirements set forth in section 5 (relating to  
24 criteria) and consists of a scientific plan of treatment that  
25 includes specified goals, a rationale and background for the  
26 plan, criteria for patient selection, specific directions for  
27 administering therapy and monitoring patients, a definition of  
28 quantitative measures for determining treatment response and  
29 methods for documenting and treating adverse reactions.

30 "Board." The Pennsylvania Cancer Clinical Trial Review Board

1 established in section 6 (relating to cancer clinical trial  
2 review board).

3 "Institutional review board" or "IRB." A board, committee or  
4 other group formally designated by an institution and approved  
5 by the National Institutes of Health, Office for Protection from  
6 Research Risks to review, approve the initiation of and conduct  
7 periodic review of biomedical research involving human subjects.  
8 The primary purpose of such review is to assure the protection  
9 of the rights and welfare of the human subjects. The term has  
10 the same meaning as the phrase "institutional review committee"  
11 as used in section 520(g) of the Federal Food, Drug, and  
12 Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.).

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

22 "Therapeutic intent." A treatment must be aimed at improving  
23 patient outcome relative to either survival or quality of life.

#### 24 Section 4. Mandated coverage.

25 Any other provision of law to the contrary notwithstanding,  
26 any health, sickness or accident policy, contract or certificate  
27 which is delivered, issued for delivery, renewed, extended or  
28 modified in this Commonwealth shall provide that benefits  
29 applicable under the policy include coverage for routine patient  
30 care costs incurred in association with approved cancer clinical

1 trials for the treatment of cancer in the same manner any other  
2 sickness, injury, disease or condition is covered under the  
3 policy, contract or certificate if the insured, enrollee or  
4 subscriber upon informed consent has been referred for such  
5 treatment by two physicians who specialize in oncology and such  
6 approved cancer clinical trials meet the requirements set forth  
7 in section 5 (relating to criteria). Routine patient care costs  
8 for services furnished by the sponsor of an approved cancer  
9 clinical trial without any charge to any participant in the  
10 approved cancer clinical trial shall not be subject to coverage  
11 under this section.

12 Section 5. Criteria.

13 Routine patient care costs for approved cancer clinical  
14 trials for cancer treatment shall be reimbursed when all of the  
15 following requirements are met:

16 (1) The treatment is provided with a therapeutic intent  
17 and is being provided pursuant to an approved cancer clinical  
18 trial that has been authorized or approved by one of the  
19 following:

- 20 (i) The National Institutes of Health.  
21 (ii) The United States Food and Drug Administration.  
22 (iii) The United States Department of Defense.  
23 (iv) The United States Department of Veterans  
24 Affairs.

25 (2) The proposed therapy has been reviewed and approved  
26 by the applicable qualified institutional review board.

27 (3) The available clinical or preclinical data indicate  
28 that the treatment provided pursuant to the approved cancer  
29 clinical trial will be at least as effective as the standard  
30 therapy and is anticipated to constitute an improvement in

1 the therapeutic effectiveness for the treatment of the  
2 disease in question.

3 Section 6. Cancer Clinical Trial Review Board.

4 (a) Establishment.--There is hereby established in the  
5 Department of Health the Pennsylvania Cancer Clinical Trial  
6 Review Board.

7 (b) Membership.--The board shall consist of nine members  
8 appointed by the Governor with the advice and consent of the  
9 Senate, as follows:

10 (1) One member shall be a physician licensed to practice  
11 medicine and surgery in this Commonwealth who specializes in  
12 oncology and is a member of a community medical oncology  
13 practice and who is not on the staff of a comprehensive or  
14 clinical cancer center designated by the National Cancer  
15 Institute.

16 (2) One member shall be a physician licensed to practice  
17 medicine and surgery in this Commonwealth who specializes in  
18 oncology and who is on the staff of a comprehensive or  
19 clinical cancer center designated by the National Cancer  
20 Institute.

21 (3) One member shall be a medical ethicist recognized  
22 for expertise in evaluating ethical implications of health  
23 care practices and procedures.

24 (4) One member shall be a medical economist recognized  
25 for expertise in evaluating economic implications of health  
26 care practices and procedures.

27 (5) One member shall be a physician licensed to practice  
28 medicine and surgery in this Commonwealth who is employed by  
29 or who represents an insurer.

30 (6) One member shall be a physician licensed to practice

1 medicine and surgery in this Commonwealth who is employed by  
2 or represents a nonprofit health care service plan.

3 (7) One member shall be a physician licensed to practice  
4 medicine and surgery in this Commonwealth who is employed by  
5 or who represents a health maintenance organization.

6 (8) One member who is a resident of this Commonwealth  
7 shall be a representative of Commonwealth residents with  
8 health insurance who are consumers of oncology services.

9 (9) One member shall be a representative of the  
10 Pennsylvania Cancer Control, Prevention and Research Advisory  
11 Board.

12 (c) Chairman.--A chairman shall be selected by a majority  
13 vote of the board members.

14 (d) Meetings.--The board shall meet no less than four times  
15 annually at the call of the chairman.

16 (e) Terms.--Members shall be appointed for four-year terms.  
17 Any vacancy occurring in the membership of the board shall be  
18 filled by a qualified person appointed by the Governor for the  
19 unexpired term of the member.

20 (f) Hearings and appeals.--The board has the power and duty  
21 to hold hearings and issue adjudications under 2 Pa.C.S. Ch. 5  
22 Subch. A (relating to practice and procedure of Commonwealth  
23 agencies) of disputes involving third-party reimbursement for  
24 patient care costs incurred in association with cancer clinical  
25 trials, subject to review and appeal in accordance with 2  
26 Pa.C.S. Ch. 7 Subch. A (relating to judicial review of  
27 Commonwealth agency action).

28 (g) Compensation and staff.--Members of the board shall  
29 receive no compensation for their services. Each member shall  
30 receive reimbursement for actual traveling expenses and other

1 necessary expenses. Administrative staffing needs shall be  
2 provided by the Department of Health. Any additional staffing  
3 needs that the board has shall be provided by the institution  
4 that provides or seeks to provide the therapeutic treatment that  
5 is under review.

6 Section 7. Construction of act.

7 Provisions of the Employee Retirement Income Security Act of  
8 1974 (Public Law 93-406, 88 Stat. 829), referred to as ERISA,  
9 currently prohibit the application of this act to certain types  
10 of health care benefit plans and health care payers. It is the  
11 intent of the General Assembly that this act be given the  
12 broadest possible application and that its scope include  
13 applications permitted by future legislative amendments and  
14 judicial interpretations of ERISA.

15 Section 8. Applicability.

16 This act shall apply to every group or individual policy,  
17 contract or certificate issued under a policy or contract of  
18 health, sickness or accident insurance delivered or issued for  
19 delivery, renewed, extended or modified in this Commonwealth,  
20 including, but not limited to, policies, contracts or  
21 certificates issued by:

22 (1) Any stock insurance company as defined in section  
23 202(c)(4) and (11) of the act of May 17, 1921 (P.L.682,  
24 No.284), known as The Insurance Company Law of 1921.

25 (2) Any mutual insurance company as defined in section  
26 202(d)(1) of The Insurance Company Law of 1921.

27 (3) A health insurance policy or contract issued by a  
28 nonprofit corporation subject to 40 Pa.C.S. Ch. 61 (relating  
29 to hospital plan corporations) or 63 (relating to  
30 professional health services plan corporations).

1           (4) A health service plan operating under the act of  
2       December 29, 1972 (P.L.1701, No.364), known as the Health  
3       Maintenance Organization Act.

4           (5) An employee welfare benefit plan as defined in  
5       section 3 of the Employee Retirement Income Security Act of  
6       1974 (Public Law 93-406, 88 Stat. 829).

7           (6) Any fraternal benefit societies as defined in  
8       Article XXIV of The Insurance Company Law of 1921.

9           (7) Any voluntary nonprofit health services plan as  
10      defined in the Health Maintenance Organization Act.

11          (8) Any preferred provider organization as defined in  
12      section 630 of The Insurance Company Law of 1921.

13          (9) Any agreement by a self-insured employer or self-  
14      insured multiple employer trust to provide health care  
15      benefits to employees and their dependents.

16          (10) Any person who sells or issues contracts or  
17      certificates of insurance which meet the requirements of this  
18      act.

19   Section 9.   Expiration.

20       This act shall expire June 30, 2010.

21   Section 10.   Effective date.

22       This act shall take effect in 180 days.