

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1198 Session of  
1997

INTRODUCED BY AFFLERBACH, WHITE, SCHWARTZ, RHOADES, COSTA,  
SALVATORE, WAGNER, MUSTO, KUKOVICH, STAPLETON, WILLIAMS,  
BELAN AND HUGHES, NOVEMBER 21, 1997

REFERRED TO BANKING AND INSURANCE, NOVEMBER 21, 1997

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  
18 insurers and other health care providers to promote the health  
19 and welfare of the people of this Commonwealth. Sound health  
20 care practices such as approved cancer clinical trials which

1 meet the requirements of this act should be available to all of  
2 the residents of this Commonwealth notwithstanding the practices  
3 and the discretion of insurers and other health care providers.  
4 The General Assembly seeks to curtail the cost of medical  
5 treatments that treat certain conditions and also seeks to  
6 pursue treatments which medical experts believe have a  
7 reasonable expectation of being at least as effective as such  
8 medical treatments.

9 Section 3. Definitions.

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

13 "Approved cancer clinical trial." A scientific study of a  
14 new therapy for the treatment of cancer in human beings that  
15 meets the requirements set forth in section 5. An "approved  
16 cancer clinical trial" consists of a scientific plan of  
17 treatment that includes specified goals, a rationale and  
18 background for the plan, criteria for patient selection,  
19 specific directions for administering therapy and monitoring  
20 patients, a definition of quantitative measures for determining  
21 treatment response and methods for documenting and treating  
22 adverse reactions.

23 "Board." The Pennsylvania Cancer Clinical Trial Review Board  
24 established in section 6.

25 "Institutional review board" or "IRB." A board, committee or  
26 other group formally designated by an institution and approved  
27 by the National Institutes of Health Office for Protection from  
28 Research Risks to review, approve the initiation of and conduct  
29 periodic review of biomedical research involving human subjects.  
30 The primary purpose of such review is to assure the protection

1 of the rights and welfare of the human subjects. The term has  
2 the same meaning as the phrase "Institutional Review Committee"  
3 as used in section 520(g) of the Federal Food, Drug, and  
4 Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.).

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

14 "Therapeutic intent." A treatment must be aimed at improving  
15 patient outcome relative to either survival or quality of life.  
16 Section 4. Mandated coverage.

17 Any other provision of law to the contrary notwithstanding,  
18 any health, sickness or accident policy, contract or certificate  
19 which is delivered, issued for delivery, renewed, extended or  
20 modified in this Commonwealth shall provide that benefits  
21 applicable under the policy include coverage for routine patient  
22 care costs incurred in association with approved cancer clinical  
23 trials for the treatment of cancer in the same manner any other  
24 sickness, injury, disease or condition is covered under the  
25 policy, contract or certificate if the insured, enrollee or  
26 subscriber upon informed consent has been referred for such  
27 treatment by two physicians who specialize in oncology and such  
28 approved cancer clinical trials meet the requirements set forth  
29 in section 5. Routine patient care costs for services furnished  
30 by the sponsor of an approved cancer clinical trial without any

1 charge to any participant in the approved cancer clinical trial  
2 shall not be subject to coverage under this section.

3 Section 5. Criteria.

4 Routine patient care costs for approved cancer clinical  
5 trials for cancer treatment shall be reimbursed when all of the  
6 following requirements are met:

7 (1) The treatment is provided with a therapeutic intent  
8 and is being provided pursuant to an approved cancer clinical  
9 trial that has been authorized or approved by one of the  
10 following:

11 (i) The National Institutes of Health.

12 (ii) The United States Food and Drug Administration.

13 (iii) The United States Department of Defense.

14 (iv) The United States Department of Veterans  
15 Affairs.

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

18 (3) The available clinical or preclinical data indicate  
19 that the treatment provided pursuant to the approved cancer  
20 clinical trial will be at least as effective as the standard  
21 therapy and is anticipated to constitute an improvement in  
22 the therapeutic effectiveness for the treatment of the  
23 disease in question.

24 Section 6. Cancer Clinical Trial Review Board.

25 (a) Establishment.--There is hereby established in the  
26 Department of Health the Pennsylvania Cancer Clinical Trial  
27 Review Board.

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

1           (1) One member shall be a physician licensed to practice  
2 medicine and surgery in this Commonwealth who specializes in  
3 oncology and is a member of a community medical oncology  
4 practice and who is not on the staff of a comprehensive or  
5 clinical cancer center designated by the National Cancer  
6 Institute.

7           (2) One member shall be a physician licensed to practice  
8 medicine and surgery in this Commonwealth who specializes in  
9 oncology and who is on the staff of a comprehensive or  
10 clinical cancer center designated by the National Cancer  
11 Institute.

12           (3) One member shall be a medical ethicist recognized  
13 for his or her expertise in evaluating ethical implications  
14 of health care practices and procedures.

15           (4) One member shall be a medical economist recognized  
16 for his or her expertise in evaluating economic implications  
17 of health care practices and procedures.

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

21           (6) One member shall be a physician licensed to practice  
22 medicine and surgery in this Commonwealth who is employed by  
23 or represents a nonprofit health care service plan.

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

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

30           (9) One member shall be a representative of the

1 Pennsylvania Cancer Control, Prevention and Research Advisory  
2 Board.

3 (c) Chairman.--A chairman will be selected by a majority  
4 vote of the board members.

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

7 (e) Terms.--Members shall be appointed for four-year terms.  
8 Any vacancy occurring in the membership of the board shall be  
9 filled by a qualified person appointed by the Governor for the  
10 unexpired term of the member.

11 (f) Hearings and appeals.--The board has the power and duty  
12 to hold hearings and issue adjudications under 2 Pa.C.S. Ch. 5  
13 Subch. A (relating to practice and procedure of Commonwealth  
14 agencies) of disputes involving third-party reimbursement for  
15 patient care costs incurred in association with cancer clinical  
16 trials, subject to review and appeal in accordance with 2  
17 Pa.C.S. Ch. 7, Subch. A (relating to judicial review of  
18 Commonwealth agency action).

19 (g) Compensation and staff.--Members of the board shall  
20 receive no compensation for their services. Each member shall  
21 receive reimbursement for actual traveling expenses and other  
22 necessary expenses. Administrative staffing needs will be  
23 provided by the Department of Health. Any additional staffing  
24 needs that the board has shall be provided by the institution  
25 that provides or seeks to provide the therapeutic treatment that  
26 is under review.

27 Section 7. Construction of act.

28 Provisions of the Employee Retirement Income Security Act of  
29 1974 (Public Law 93-406, 88 Stat. 829), referred to as ERISA,  
30 currently prohibit the application of this act to certain types

1 of health care benefit plans and health care payers. It is the  
2 intent of the General Assembly that this act be given the  
3 broadest possible application and that its scope include  
4 applications permitted by future legislative amendments and  
5 judicial interpretations of ERISA.

6 Section 8. Applicability.

7 This act shall apply to every group or individual policy,  
8 contract or certificate issued under a policy or contract of  
9 health, sickness or accident insurance delivered or issued for  
10 delivery, renewed, extended or modified in this Commonwealth,  
11 including, but not limited to, policies, contracts or  
12 certificates issued by:

13 (1) Any stock insurance company as defined in section  
14 202(c)(4) and (11) of the act of May 17, 1921 (P.L.682,  
15 No.284), known as The Insurance Company Law of 1921.

16 (2) Any mutual insurance company as defined in section  
17 202(d)(1) of The Insurance Company Law of 1921.

18 (3) A health insurance policy or contract issued by a  
19 nonprofit corporation subject to 40 Pa.C.S. Chs. 61 (relating  
20 to hospital plan corporations) or 63 (relating to  
21 professional health services plan corporations).

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

25 (5) An employee welfare benefit plan as defined in  
26 section 3 of the Employee Retirement Income Security Act of  
27 1974 (Public Law 93-406, 88 Stat. 829).

28 (6) Any fraternal benefit societies as defined in the  
29 act of December 14, 1992 (P.L.835, No.134), known as the  
30 Fraternal Benefit Societies Code.

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

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

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

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

11 Section 9. Expiration.

12 This act shall expire June 30, 2005.

13 Section 10. Effective date.

14 This act shall take effect in 180 days.