

---

THE GENERAL ASSEMBLY OF PENNSYLVANIA

---

**SENATE BILL**

**No. 163**      Session of  
2003

---

INTRODUCED BY SCHWARTZ, LAVALLE, C. WILLIAMS, WAGNER, MUSTO,  
TARTAGLIONE, COSTA, ORIE, KITCHEN, STOUT, LOGAN AND KASUNIC,  
FEBRUARY 4, 2003

---

REFERRED TO BANKING AND INSURANCE, FEBRUARY 4, 2003

---

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 Scientists believe that higher participation in cancer clinical  
5 trials will lead to faster development of therapies for those in  
6 need. For decades well over 50% of pediatric cancer patients  
7 were enrolled in clinical trials, and today, 75% of cancers in  
8 children are curable. In 2000, about 600 cancer clinical trials  
9 were in progress, but only 45,000 cancer patients were enrolled.  
10 If more health care providers covered these trials, more people  
11 would participate. Coverage for clinical trials would lead to  
12 new therapies and treatments as well as help cancer patients in  
13 this Commonwealth.

14 Section 3. Definitions.

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

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

27 "Board." The Pennsylvania Cancer Clinical Trial Review Board  
28 established in section 6.

29 "Institutional review board" or "IRB." A board, committee or  
30 other group formally designated by an institution and approved

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

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

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

21 Any other provision of law to the contrary notwithstanding,  
22 any health, sickness or accident policy, contract or certificate  
23 which is delivered, issued for delivery, renewed, extended or  
24 modified in this Commonwealth shall provide that benefits  
25 applicable under the policy include coverage for routine patient  
26 care costs incurred in association with approved cancer clinical  
27 trials for the treatment of cancer in the same manner any other  
28 sickness, injury, disease or condition is covered under the  
29 policy, contract or certificate if the insured, enrollee or  
30 subscriber upon informed consent has been referred for such

1 treatment by two physicians who specialize in oncology and such  
2 approved cancer clinical trials meet the requirements set forth  
3 in section 5. Routine patient care costs for services furnished  
4 by the sponsor of an approved cancer clinical trial without any  
5 charge to any participant in the approved cancer clinical trial  
6 shall not be subject to coverage under this section.

7 Section 5. Criteria.

8 Routine patient care costs for approved cancer clinical  
9 trials for cancer treatment shall be reimbursed when all of the  
10 following requirements are met:

11 (1) The treatment is provided with a therapeutic intent  
12 and is being provided pursuant to an approved cancer clinical  
13 trial that has been authorized or approved by one of the  
14 following:

15 (i) The National Institutes of Health.

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

17 (iii) The United States Department of Defense.

18 (iv) The United States Department of Veterans  
19 Affairs.

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

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

28 Section 6. Cancer Clinical Trial Review Board.

29 (a) Establishment.--There is hereby established in the  
30 Department of Health the Pennsylvania Cancer Clinical Trial

1 Review Board.

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

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

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

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

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

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

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

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

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

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

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

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

11 (e) Terms.--Members shall be appointed for four-year terms.  
12 Any vacancy occurring in the membership of the board shall be  
13 filled by a qualified person appointed by the Governor for the  
14 unexpired term of the member.

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

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

1 Section 7. Construction of act.

2 Provisions of the Employee Retirement Income Security Act of  
3 1974 (Public Law 93-406, 88 Stat. 829), referred to as ERISA,  
4 currently prohibit the application of this act to certain types  
5 of health care benefit plans and health care payers. It is the  
6 intent of the General Assembly that this act be given the  
7 broadest possible application and that its scope include  
8 applications permitted by future legislative amendments and  
9 judicial interpretations of ERISA.

10 Section 8. Applicability.

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

17 (1) Any stock insurance company as defined in section  
18 202(c)(4) and (11) of the act of May 17, 1921 (P.L.682,  
19 No.284), known as The Insurance Company Law of 1921.

20 (2) Any mutual insurance company as defined in section  
21 202(d)(1) of The Insurance Company Law of 1921.

22 (3) A health insurance policy or contract issued by a  
23 nonprofit corporation subject to 40 Pa.C.S. Ch. 61 (relating  
24 to hospital plan corporations) or 63 (relating to  
25 professional health services plan corporations).

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

29 (5) An employee welfare benefit plan as defined in  
30 section 3 of the Employee Retirement Income Security Act of

1 1974 (Public Law 93-406, 88 Stat. 829).

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

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

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

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

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

14 Section 9. Expiration.

15 This act shall expire June 30, 2008.

16 Section 10. Effective date.

17 This act shall take effect in 180 days.