
THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 275 Session of
2007

INTRODUCED BY O'PAKE, COSTA, LAVALLE, BOSCOLA, RHOADES, MUSTO,
FONTANA, TARTAGLIONE, ORIE, STOUT, WOZNIAK, RAFFERTY,
KASUNIC, WASHINGTON, ERICKSON, KITCHEN, C. WILLIAMS AND
LOGAN, MARCH 8, 2007

REFERRED TO BANKING AND INSURANCE, MARCH 8, 2007

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 Notwithstanding any other provision of law, every health care
22 policy delivered, renewed, extended or modified in this
23 Commonwealth shall include coverage for routine patient care
24 costs incurred in approved clinical trials for cancer treatment
25 to the same degree as in treating any other sickness, injury,
26 disease or condition covered under the policy when the insured
27 has been referred for such treatment by two physicians who
28 specialize in oncology and the trials meet the requirements set
29 forth in section 5. Routine patient care costs for services
30 furnished without charge to any participant in the trial shall

1 not be subject to coverage under this section.

2 Section 5. Criteria.

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

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

10 (i) The National Institutes of Health.

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

12 (iii) The United States Department of Defense.

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

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

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

23 Section 6. Cancer Clinical Trial Review Board.

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

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

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

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

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

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

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

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

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

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

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

29 (9) One member shall be a representative of the
30 Pennsylvania Cancer Control, Prevention and Research Advisory

1 Board.

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

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

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

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

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

26 Section 7. Construction of act.

27 Provisions of the Employee Retirement Income Security Act of
28 1974 (Public Law 93-406, 88 Stat. 829), referred to as ERISA,
29 currently prohibit the application of this act to certain types
30 of health care benefit plans and health care payers. It is the

1 intent of the General Assembly that this act be given the
2 broadest possible application and that its scope include
3 applications permitted by future legislative amendments and
4 judicial interpretations of ERISA.

5 Section 8. Applicability.

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

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

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

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

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

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

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

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

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

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

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

9 Section 9. Expiration.

10 This act shall expire June 30, 2012.

11 Section 10. Effective date.

12 This act shall take effect in 180 days.