

1 AN ACT concerning tobacco settlement proceeds.

2 Be it enacted by the People of the State of Illinois,
3 represented in the General Assembly:

4 Section 1. Short title. This Act may be cited as the
5 Tobacco Settlement Proceeds for Investigational Clinical
6 Cancer Trials Act.

7 Section 5. Use of tobacco settlement proceeds. Because a
8 cure for cancer has not been discovered, up to 10% of the
9 amounts received by the State pursuant to a tobacco
10 settlement agreement shall be dedicated to assist in the
11 payment for services provided under a qualified
12 investigational clinical cancer trial program in Illinois.

13 Section 10. Definitions. In this Act:

14 "External independent review process" means the appeals
15 and external independent review process as provided in
16 Section 45 of the Managed Care Reform and Patient Rights Act.

17 "Physician" means a board certified oncologist.

18 "Program" means the qualified investigational clinical
19 cancer trial program established under Section 15.

20 "Qualified investigational clinical cancer trial" means a
21 treatment (i) the effectiveness of which has not been
22 determined and (ii) that is under clinical investigation as
23 part of an approved National Institutes of Health or National
24 Cancer Institute sponsored Phase III or Phase IV research
25 trial.

26 "Research costs" means costs that are (i) associated with
27 conducting the qualified investigational clinical cancer
28 trial, including but not limited to data collection and
29 management, physician and nurse research time, analysis of
30 results, and tests performed purely for research purposes and

1 (ii) usually covered by the sponsoring organization.

2 "Routine patient care costs" means costs for those
3 medical services and supplies rendered pursuant to physician
4 orders which are necessary to conduct the qualified
5 investigational clinical trial. "Routine patient care costs"
6 do not include the following:

7 (1) The costs of items or services normally paid
8 for by other funding sources, such as the investigational
9 drugs, pharmaceuticals, or devices themselves, any
10 nonhealth services that might be required for a patient
11 to receive the cancer treatment, and the managing of the
12 research trial.

13 (2) Costs associated with the provision of any
14 goods, services, or benefits that generally are furnished
15 without charge in connection with such an investigational
16 clinical cancer trial program for treatment of cancer
17 costs.

18 (3) Costs related to any service, supply, or device
19 that has been ordered solely for the convenience of the
20 patient.

21 "Standard of care" means that level of care a physician
22 would provide under like or similar circumstances.

23 "Tobacco settlement agreement" means the Master
24 Settlement Agreement in the case of People of the State of
25 Illinois v. Philip Morris et al. (Circuit Court of Cook
26 County, No. 96-L13146). The term also includes any
27 settlement with or judgment against a tobacco product
28 manufacturer not participating in that Master Settlement
29 Agreement, if the settlement or judgment is in satisfaction
30 of a released claim as that term is defined in the Master
31 Settlement Agreement.

32 Section 15. Investigational clinical cancer trial
33 program. The Department of Public Health shall establish and

1 administer a program to pay for patient care costs associated
2 with participation in a qualified investigational cancer
3 trial when those costs are not otherwise reimbursed. The
4 Department of Public Health shall establish eligibility
5 standards and an application process by rule.

6 Section 20. Participation in program. Participation in
7 the program shall be limited to persons who meet the
8 following criteria:

9 (1) The person is a cancer patient who, according
10 to the current diagnosis of the patient's physician, has
11 a high probability of death within 2 years.

12 (2) The patient's physician certifies that the
13 patient has the condition described in paragraph (1) and
14 all of the following situations are applicable:

15 (A) Standard therapies have not been effective
16 in improving the patient's condition.

17 (B) Standard therapies are not medically
18 appropriate for the patient.

19 (C) In the case of an insured patient, there
20 is no standard therapy covered by the health insurer
21 that is more beneficial than the therapy.

22 (3) The patient's physician has recommended a drug,
23 device, procedure, or other therapy that in the
24 physician's opinion would be more beneficial to the
25 patient. These recommendations must be based on the
26 physician's written certification based on the generally
27 accepted standard of care.

28 (4) The patient has been denied coverage by his or
29 her health insurance plan for a drug, device, procedure,
30 or other therapy recommended or requested pursuant to
31 paragraph (3) based on a finding by the health insurance
32 plan that the treatment was experimental or
33 investigational.

1 (5) The patient has participated in an external
2 independent review process that has resulted in a finding
3 in favor of recommending the patient into a qualified
4 clinical trial.

5 (6) The patient is an Illinois resident who has
6 resided in Illinois for at least 12 months.

7 Section 20. Payments under the program.

8 (a) Payment shall be made under the program to or on
9 behalf of a program eligible patient only for costs not
10 reimbursed or eligible for reimbursement by any other third
11 party or governmental entity (including, without limitation,
12 private or group insurance, Medicaid, Medicare, and the
13 Veterans Administration). The Director of Public Health may,
14 however, waive this requirement in individually considered
15 cases if the Director determines that its enforcement will
16 deny services to a class of cancer patients because of
17 conflicting State or federal laws or regulations.

18 (b) The Director of Public Health may restrict or
19 categorize reimbursements to meet budgetary limitations.

20 Section 25. List of trials. The Director of Public Health
21 shall maintain a list of qualified investigational cancer
22 trials. The Director of Public Health shall establish an
23 internal review procedure for updating the list. The
24 procedure shall allow the addition and deletion of qualified
25 investigational clinical cancer trials to the list. The
26 internal review procedure shall take place at least once
27 during each fiscal year.

28 Section 30. Effect of Act.

29 (a) Nothing in this Act shall be construed to prohibit
30 any health insurance plan from applying cost sharing
31 arrangements, limitations, or exclusions.

1 (b) This Act does not relieve the sponsor of a qualified
2 investigational clinical cancer trial program of financial
3 responsibility for the accepted costs of the program, such as
4 research costs.

5 (c) This Act does not relieve a health insurance plan of
6 financial responsibility for routine patient care costs for
7 the treatment of cancer if the health insurance plan provides
8 coverage for cancer.

9 Section 99. Effective date. This Act takes effect upon
10 becoming law.