AN ACT concerning tobacco settlement proceeds.

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

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

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

Section 10. Definitions. In this Act:

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

"Physician" means a board certified oncologist.

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

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

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

(ii) usually covered by the sponsoring organization.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 17. Payments under the program.

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

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

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

Section 30. Effect of Act.

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

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

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

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