

1 AN ACT concerning health.

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 Cancer
5 Clinical Trial Participation Program Act.

6 Section 5. Findings. The General Assembly finds that:

7 (1) The ability to translate medical findings from
8 research to practice relies largely on robust subject
9 participation and a diverse subject participation pool in
10 clinical trials.

11 (2) Diverse subject participation in cancer clinical
12 trials depends significantly on whether an individual is
13 able to afford ancillary costs, including transportation
14 and lodging, during the course of participation in a cancer
15 clinical trial.

16 (3) A national study conducted in 2015 found that
17 individuals from households with an annual income of less
18 than \$50,000 were 30% less likely to participate in cancer
19 clinical trials.

20 (4) Direct and indirect costs, including
21 transportation, lodging, and child-care expenses, prevent
22 eligible individuals from participating in cancer clinical
23 trials according to the National Cancer Institute.

1 (5) The disparities in subject participation in cancer
2 clinical trials threaten the basic ethical underpinning of
3 clinical research, which requires the benefits of the
4 research to be made available equitably among all eligible
5 individuals.

6 (6) While the United States Food and Drug
7 Administration recently confirmed to Congress and provided
8 guidance on its website that reimbursement of direct
9 subject-incurred expenses is not an undue inducement, many
10 organizations, research sponsors, philanthropic
11 individuals, charitable organizations, governmental
12 entities, and other persons still operate under the
13 misconception that such reimbursement is an undue
14 inducement.

15 (7) It is the intent of the General Assembly to enact
16 legislation to further define and establish a clear
17 difference between items considered to be an undue
18 inducement for a subject to participate in a cancer
19 clinical trial and the reimbursement of expenses for
20 participating in a cancer clinical trial.

21 (8) Further clarification of the United States Food and
22 Drug Administration's confirmation and guidance is
23 appropriate and important to improve subject participation
24 in cancer clinical trials, which is the primary intent of
25 this legislation.

1 Section 10. Definitions. In this Act:

2 "Cancer clinical trial" means a research study that
3 subjects an individual to a new cancer treatment, including a
4 medication, chemotherapy, adult stem cell therapy, or other
5 treatment.

6 "Cancer clinical trial sponsor" means a person, physician,
7 professor, or researcher who initiates a cancer clinical trial;
8 a government entity or agency that initiates a cancer clinical
9 trial; or an industry, including, but not limited to, a
10 pharmaceutical, biotechnology, or medical device company, that
11 initiates a cancer clinical trial.

12 "Independent third-party organization" means an entity or
13 organization, whether public or private, that is not a sponsor
14 or host of a cancer clinical trial, or in any way directly
15 affiliated with a sponsor or host of a cancer clinical trial,
16 and has experience in patient advocacy and direct patient
17 reimbursement of cancer clinical trial participation costs.

18 "Inducement" means providing a person something of value,
19 including money, as part of participation in a clinical trial.

20 "Program" means the cancer clinical trial participation
21 program established under this Act.

22 "Subject" means an individual who participates in the
23 program.

24 "Undue inducement" means the value of something received by
25 a potential clinical trial research subject, which value is so
26 large that it causes the research subject to take risks that

1 are not in his or her best interests.

2 Section 15. Establishment. An independent third-party
3 organization may develop and implement the cancer clinical
4 trial participation program to provide reimbursement to
5 subjects for ancillary costs associated with participation in a
6 cancer clinical trial, including costs for:

7 (1) travel;

8 (2) lodging;

9 (3) parking and tolls; and

10 (4) other costs considered appropriate by the
11 organization.

12 Section 20. Requirements; notice.

13 (a) The program:

14 (1) must collaborate with physicians, health care
15 providers, and cancer clinical trial sponsors to notify a
16 prospective subject about the program when:

17 (A) the prospective subject consents to a cancer
18 clinical trial; or

19 (B) funding is available to provide the program for
20 the cancer clinical trial in which the prospective
21 subject participates;

22 (2) must reimburse subjects based on financial need,
23 which may include reimbursement to subjects whose income is
24 at or below 700% of the federal poverty level;

1 (3) must provide reimbursement for ancillary costs,
2 including costs described under Section 15, to eliminate
3 the financial barriers to enrollment in a cancer clinical
4 trial;

5 (4) may provide reimbursement for reasonable ancillary
6 costs, including costs described under Section 15, to one
7 family member, friend, or other person who attends a cancer
8 clinical trial to support a subject; and

9 (5) must comply with applicable federal and State laws.

10 (b) The independent third-party organization administering
11 the program shall provide written notice to prospective
12 subjects of the requirements described under subsection (a).

13 Section 25. Reimbursement requirements; notice.

14 (a) A reimbursement under the program at a trial site that
15 conducts cancer clinical trials must:

16 (1) be reviewed and approved by the institutional
17 review board associated with the cancer clinical trial for
18 which the reimbursement is provided; and

19 (2) comply with applicable federal and State laws.

20 (b) The independent third-party organization operating the
21 program is not required to obtain approval from an
22 institutional review board on the financial eligibility of a
23 subject who is medically eligible for a cancer clinical trial.

24 (c) The independent third-party organization operating the
25 program shall provide written notice to a subject on:

1 (1) the nature and availability of the ancillary
2 financial support under the program; and

3 (2) the program's general guidelines on financial
4 eligibility.

5 Section 30. Reimbursement status as undue inducement.
6 Reimbursement to a subject of ancillary costs under the
7 program:

8 (1) does not constitute an undue inducement to
9 participate in a cancer clinical trial;

10 (2) is not considered coercion or the exertion of undue
11 influence to participate in a cancer clinical trial; and

12 (3) is meant to accomplish parity in access to cancer
13 clinical trials and remove barriers to participation in
14 cancer clinical trials for financially burdened subjects.

15 Section 35. Funding. The independent third-party
16 organization that administers the program may accept gifts,
17 grants, and donations from any public or private source to
18 implement this Act.

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