

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 5. The Cancer Clinical Trial Participation Program
5 Act is amended by changing Sections 1, 5, 10, 15, 20, 25, and
6 30 as follows:

7 (410 ILCS 416/1)

8 Sec. 1. Short title. This Act may be cited as the ~~Cancer~~
9 Clinical Trial Participation Program Act.

10 (Source: P.A. 101-619, eff. 12-20-19.)

11 (410 ILCS 416/5)

12 Sec. 5. Findings. The General Assembly finds that:

13 (1) The ability to translate medical findings from
14 research to practice relies largely on robust subject
15 participation and a diverse subject participation pool in
16 clinical trials.

17 (2) Diverse subject participation in ~~cancer~~ clinical
18 trials depends significantly on whether an individual is
19 able to afford ancillary costs, including transportation
20 and lodging, during the course of participation in a
21 ~~cancer~~ clinical trial.

22 (3) A national study conducted in 2015 found that

1 individuals from households with an annual income of less
2 than \$50,000 were 30% less likely to participate in ~~cancer~~
3 clinical trials.

4 (4) Direct and indirect costs, including
5 transportation, lodging, and child-care expenses, prevent
6 eligible individuals from participating in ~~cancer~~ clinical
7 trials according to the National Cancer Institute.

8 (5) The disparities in subject participation in ~~cancer~~
9 clinical trials threaten the basic ethical underpinning of
10 clinical research, which requires the benefits of the
11 research to be made available equitably among all eligible
12 individuals.

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

22 (7) It is the intent of the General Assembly to enact
23 legislation to further define and establish a clear
24 difference between items considered to be an undue
25 inducement for a subject to participate in a ~~cancer~~
26 clinical trial and the reimbursement of expenses for

1 participating in a ~~cancer~~ clinical trial.

2 (8) Further clarification of the United States Food
3 and Drug Administration's confirmation and guidance is
4 appropriate and important to improve subject participation
5 in ~~cancer~~ clinical trials, which is the primary intent of
6 this legislation.

7 (Source: P.A. 101-619, eff. 12-20-19.)

8 (410 ILCS 416/10)

9 Sec. 10. Definitions. In this Act:

10 "Clinical ~~Cancer-clinical~~ trial" means (i) a research
11 study that subjects an individual to a new cancer treatment,
12 including a medication, chemotherapy, adult stem cell therapy,
13 or other treatment or (ii) a voluntary research study
14 conducted on people and designed to answer specific questions
15 about the safety or effectiveness of a drug, vaccine, therapy,
16 medical device, medical diagnostic, or new way of using an
17 existing treatment to treat or diagnose a condition.

18 "Clinical ~~Cancer-clinical~~ trial sponsor" means a person,
19 physician, professor, or researcher who initiates a ~~cancer~~
20 clinical trial; a government entity or agency that initiates a
21 ~~cancer~~ clinical trial; or an industry, including, but not
22 limited to, a pharmaceutical, biotechnology, or medical device
23 company, that initiates a ~~cancer~~ clinical trial.

24 "Condition" means a disease, disorder, syndrome, illness,
25 or injury, including, but not limited to, cancer,

1 cardiovascular disease, circulatory disease, infectious
2 disease, digestive disease, musculoskeletal disease, nervous
3 system disease, endocrinological disease, metabolic disease,
4 mental health and behavioral disorder, blood disease, and rare
5 diseases.

6 "Independent third-party organization" means an entity or
7 organization, whether public or private, that is not a sponsor
8 or host of a ~~cancer~~ clinical trial, or that is not in any way
9 directly affiliated with a sponsor or host of a ~~cancer~~
10 clinical trial, and has experience in patient advocacy and
11 direct patient reimbursement of ~~cancer~~ clinical trial
12 participation costs.

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

15 "Program" means the ~~cancer~~ clinical trial participation
16 program established under this Act.

17 "Subject" means an individual who participates in the
18 program.

19 "Undue inducement" means the value of something received
20 by a potential clinical trial research subject, which value is
21 so large that it may reasonably cause ~~causes~~ the research
22 subject to take risks that are not in his or her best
23 interests.

24 (Source: P.A. 101-619, eff. 12-20-19.)

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

6 (1) travel;

7 (2) lodging;

8 (3) parking and tolls; and

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

11 (Source: P.A. 101-619, eff. 12-20-19.)

12 (410 ILCS 416/20)

13 Sec. 20. Requirements; notice.

14 (a) The program:

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

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

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

23 (2) must reimburse subjects based on financial need,
24 which may include reimbursement to subjects whose income
25 is 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
8 ~~cancer~~ clinical trial to support a subject; and

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

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

14 (Source: P.A. 101-619, eff. 12-20-19.)

15 (410 ILCS 416/25)

16 Sec. 25. Reimbursement requirements; notice.

17 (a) A reimbursement under the program at a trial site that
18 conducts ~~cancer~~ clinical trials must:

19 (1) be reviewed and approved by the institutional
20 review board associated with the ~~cancer~~ clinical trial for
21 which the reimbursement is provided; and

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

23 (b) The independent third-party organization operating the
24 program is not required to obtain approval from an
25 institutional review board with respect to ~~on~~ the financial

1 eligibility of a subject who is medically eligible for a
2 ~~cancer~~ clinical trial.

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

5 (1) the nature, ~~and~~ availability, and scope of the
6 ancillary financial support under the program; and

7 (2) the program's general guidelines on financial
8 eligibility.

9 (Source: P.A. 101-619, eff. 12-20-19.)

10 (410 ILCS 416/30)

11 Sec. 30. Reimbursement status as undue inducement.
12 Reimbursement of ancillary costs incurred by ~~to~~ a subject ~~of~~
13 ~~ancillary costs~~ under the program:

14 (1) does not constitute an undue inducement to
15 participate in a ~~cancer~~ clinical trial;

16 (2) is not considered coercion or the exertion of
17 undue influence to participate in a ~~cancer~~ clinical trial;
18 and

19 (3) shall be deemed ~~is meant~~ to accomplish parity in
20 access to ~~cancer~~ clinical trials and remove barriers to
21 participation in ~~cancer~~ clinical trials for financially
22 burdened subjects.

23 (Source: P.A. 101-619, eff. 12-20-19.)

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