# SB1774

LRB10304737CPF49746b

## 103RD GENERAL ASSEMBLY

## State of Illinois

## 2023 and 2024

### SB1774

Introduced 2/9/2023, by Sen. Adriane Johnson

## SYNOPSIS AS INTRODUCED:

410 ILCS 416/1
410 ILCS 416/5
410 ILCS 416/10
410 ILCS 416/15
410 ILCS 416/20
410 ILCS 416/25
410 ILCS 416/30

Amends the Cancer Clinical Trial Participation Program Act. Changes the short title of the Act to the Clinical Trial Participation Program Act. Throughout the Act, replaces references to "cancer clinical trial" with references to "clinical trial" and makes conforming changes. Provides that "clinical trial" includes a voluntary research study conducted on people and designed to answer specific questions about the safety or effectiveness of a drug, vaccine, therapy, medical device, medical diagnostic, or new way of using an existing treatment to treat or diagnose a condition. Defines "condition". Makes other changes. Effective immediately.

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A BILL FOR

AN ACT concerning health.

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

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

(410 ILCS 416/1)

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

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

(410 ILCS 416/5)

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

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

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

(3) A national study conducted in 2015 found that

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

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

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

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

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

participating in a ~~cancer~~ clinical trial.

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

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

(410 ILCS 416/10)

Sec. 10. Definitions. In this Act:

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

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

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

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

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

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

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

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

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

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

(410 ILCS 416/15)

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

(1) travel;

(2) lodging;

(3) parking and tolls; and

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

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

(410 ILCS 416/20)

Sec. 20. Requirements; notice.

(a) The program:

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

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

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

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

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

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

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

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

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

(410 ILCS 416/25)

Sec. 25. Reimbursement requirements; notice.

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

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

(2) comply with applicable federal and State laws.

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

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

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

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

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

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

(410 ILCS 416/30)

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

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

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

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

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

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