BILL ANALYSIS

Senate Research Center
89R13815 TYPED

S.B. 1357
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As Filed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Currently, the authority to implement the cancer clinical trial participation program established by the 86th Legislature under Cancer Prevention and Research Institute of Texas (CPRIT) lies with an "independent, third-party organization." Up until recently, Lazarex Cancer Foundation was performing as that independent third party. Last year, Lazerex stepped away from their role with CPRIT and the Clinical Trial Participation Program leaving CPRIT to manage the implementation of the program through participating institutions, UT Southwestern Medical Center and Baylor College of Medicine.

Subjects enrolled in these clinical trials receive reimbursements for ancillary expenses related to their participation, such as lodging, parking, and tolls. Over the past seven years, CPRIT has engaged in extensive discussions with trial participants, gaining firsthand insight into the challenges they face. In particular, food and childcare have emerged as significant additional stressors during their trial process.

This recent shift in program administration has highlighted the need for greater flexibility in how the Cancer Clinical Trial Participation Program is managed and expanded.

In response, S.B. 1357 aims to broaden the entities eligible to administer the program, ensuring its continued effectiveness and accessibility. Additionally, the bill addresses the critical gaps identified through CPRIT's engagement with trial participants by expanding the scope of reimbursable ancillary costs—further reducing financial barriers to participation.

S.B. 1357 seeks to include a private postsecondary educational institution, as defined by Section 61.302, Education Code; an institution of higher education, as defined by Section 61.003, Education Code; and an independent research organization located in this state on top of third party organization for the purpose of administration of the Cancer Clinical Trial Program.

S.B. 1357 also adds meals or groceries and child care to the ancillary costs that may be reimbursed by the program administrator for a trial participant.

As proposed, S.B. 1357 amends current law relating to a cancer clinical trial participation program.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Provides that the legislature 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 percent 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 Internet website that reimbursement of direct subject-incurred expenses is not an inducement, many organizations, research sponsors, philanthropic individuals, charitable organizations, governmental entities, and other persons still operate under the misconception that such reimbursement is an inducement;

(7) it is the intent of the legislature to enact legislation to further define and establish a clear difference between items considered to be an inducement for a subject to participate in a cancer clinical trial and the reimbursement of expenses for participating in a cancer clinical trial; and

(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.

SECTION 2. Amends Subtitle B, Title 2, Health and Safety Code, by adding Chapter 50, as follows:

CHAPTER 50. CANCER CLINICAL TRIAL PARTICIPATION PROGRAM

Sec. 50.0001. DEFINITIONS. Defines "cancer clinical trial," "inducement," "program," and "subject."

Sec. 50.0002. ESTABLISHMENT. Authorizes a public or private institution of higher education, as defined by Section 61.003 (Definitions), Education Code, an independent research organization located in Texas, or an independent, third-party organization to 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 certain living expenses.

Sec. 50.0003. REQUIREMENTS; NOTICE. (a) Provides that the cancer clinical trial participation program (program) is:

(1) required to collaborate with physicians and health care providers to notify a prospective subject about the program when the prospective subject provides informed consent for a cancer clinical trial or funding is available to provide the program for the cancer clinical trial in which the prospective subject participates;

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

(3) required to provide reimbursement for ancillary costs, including costs described by Section 50.0002, to eliminate the financial barriers to enrollment in a clinical trial;

(4) authorized to provide reimbursement for reasonable ancillary costs, including costs described by Section 50.0002, to one family member, friend, or other person who attends a cancer clinical trial to support a subject; and

(5) required to comply with applicable federal and state laws.

(b) Requires the public or private institution of higher education, as defined by Section 61.003, Education Code, the independent research organization located in Texas, or the independent, third-party organization administering the program to provide written notice to prospective subjects of the requirements described by Subsection (a).

Sec. 50.0004. REIMBURSEMENT REQUIREMENTS; NOTICE. (a) Requires that a reimbursement under the program be reviewed and approved by the institutional review board associated with the cancer clinical trial for the reimbursement is provided, and comply with applicable federal and state laws.

(b) Provides that the independent, third-party organization operating the program is not required to obtain approval from an institutional review board on the financial eligibility of a subject who is medically eligible for the program.

(c) Requires the public or private institution of higher education, as defined by Section 61.003, Education Code, the independent research organization located in Texas, or the independent, third-party organization operating the program to provide written notice to a subject on the nature and availability of the ancillary financial support under the program and the program's general guidelines on financial eligibility.

Sec. 50.0005. REIMBURSEMENT STATUS AS INDUCEMENT. Provides that reimbursement to a subject of ancillary costs under the program:

(1) does not constitute an 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) is meant to accomplish parity in access to cancer clinical trials and remove barriers to participation in cancer clinical trials for financially burdened subjects.

Sec. 50.0006. FUNDING. Authorizes the public or private institution of higher education, as defined by Section 61.003, Education Code, the independent research organization located in Texas, or the independent, third-party organization that administers the program to accept gifts, grants, and donations from any public or private source to implement this chapter.

Sec. 50.0007. COLLABORATION. Authorizes the public or private institution of higher education, as defined by Section 61.003, Education Code, the independent research organization located in Texas, or the independent, third-party organization that administers the program to collaborate with the Cancer Prevention and Research Institute of Texas established under Chapter 102 (Cancer Prevention and Research Institute of Texas) to provide reimbursement under the program.