By: Parker S.B. No. 1357

A BILL TO BE ENTITLED

AN ACT

relating to a cancer clinical trial participation program.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. 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. Subtitle B, Title 2, Health and Safety Code, is amended by adding Chapter 50 to read as follows:

CHAPTER 50. CANCER CLINICAL TRIAL PARTICIPATION PROGRAM

Sec. 50.0001. DEFINITIONS. In this chapter:

(1) "Cancer clinical trial" means a research study that subjects an individual to a new cancer treatment, including a medication, chemotherapy, adult stem cell therapy, or other treatment.

(2) "Inducement" means the payment of money, including a lump-sum or salary payment, to an individual for the individual's participation in a cancer clinical trial.

(3) "Program" means the cancer clinical trial participation program established under this chapter.

(4) "Subject" means an individual who participates in the program.

Sec. 50.0002. ESTABLISHMENT. A public or private institution of higher education, as defined by Section 61.003, Education Code, an independent research organization located in Texas, or ~~An~~ 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;

(4) meals or groceries;

(5) childcare; and

~~(4)~~ (6) other costs considered appropriate by the organization.

Sec. 50.0003. REQUIREMENTS; NOTICE. (a) The program:

(1) must collaborate with physicians and health care providers to notify a prospective subject about the program when:

(A) the prospective subject provides informed consent for 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 percent of the federal poverty level;

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

(4) may 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) must comply with applicable federal and state laws.

(b) 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 shall provide written notice to prospective subjects of the requirements described by Subsection (a).

Sec. 50.0004. REIMBURSEMENT REQUIREMENTS; NOTICE. (a) A reimbursement under the program 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 on the financial eligibility of a subject who is medically eligible for the program.

(c) 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 shall provide written notice to a subject on:

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

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

Sec. 50.0005. REIMBURSEMENT STATUS AS INDUCEMENT. 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. 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 may accept gifts, grants, and donations from any public or private source to implement this chapter.

Sec. 50.0007. COLLABORATION. 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 may collaborate with the Cancer Prevention and Research Institute of Texas established under Chapter 102 to provide reimbursement under the program.