

By: Parker

H.B. No. 3147

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 partly 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 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 that reimbursement

1 of direct subject-incurred expenses is not an inducement, many  
2 organizations, research sponsors, philanthropic individuals,  
3 charitable organizations, governmental entities, and other persons  
4 still believe that such reimbursement is an inducement;

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

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

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

16 CHAPTER 50. CANCER CLINICAL TRIAL PARTICIPATION PROGRAM

17 Sec. 50.0001. DEFINITIONS. In this chapter:

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

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

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

27 (4) "Subject" means an individual who participates in

1 the program.

2 Sec. 50.0002. ESTABLISHMENT. A nonprofit organization may  
3 develop and implement the cancer clinical trial participation  
4 program to provide reimbursement to subjects for ancillary costs  
5 associated with participation in a cancer clinical trial, including  
6 costs for:

7 (1) travel;

8 (2) lodging;

9 (3) child care; and

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

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

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

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

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

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

25 (b) The nonprofit organization administering the program  
26 shall provide written notice to prospective subjects of the  
27 requirements described by Subsection (a).

1       Sec. 50.0004. REIMBURSEMENT REQUIREMENTS; NOTICE. (a) A  
2 reimbursement under the program must:

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

6           (2) comply with applicable federal and state laws.

7       (b) The nonprofit organization operating the program is not  
8 required to obtain approval from an institutional review board on  
9 the financial eligibility of a subject who is medically eligible  
10 for the program.

11       (c) The nonprofit organization operating the program shall  
12 provide written notice to a subject on:

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

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

17       Sec. 50.0005. REIMBURSEMENT STATUS AS INDUCEMENT.  
18 Reimbursement to a subject through the program does not constitute  
19 an inducement or coercion to participate in a cancer clinical  
20 trial.

21       Sec. 50.0006. FUNDING. The nonprofit organization that  
22 administers the program may accept gifts, grants, and donations  
23 from any public or private source to implement this chapter.

24       SECTION 3. This Act takes effect September 1, 2019.