

By: Parker, et al.

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 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

1 Administration recently confirmed to Congress and provided
2 guidance on its Internet website that reimbursement of direct
3 subject-incurred expenses is not an inducement, many
4 organizations, research sponsors, philanthropic individuals,
5 charitable organizations, governmental entities, and other persons
6 still operate under the misconception that such reimbursement is an
7 inducement;

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

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

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

19 CHAPTER 50. CANCER CLINICAL TRIAL PARTICIPATION PROGRAM

20 Sec. 50.0001. DEFINITIONS. In this chapter:

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

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

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

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

5 Sec. 50.0002. ESTABLISHMENT. An independent, third-party
6 organization may develop and implement the cancer clinical trial
7 participation program to provide reimbursement to subjects for
8 ancillary costs associated with participation in a cancer clinical
9 trial, including costs for:

10 (1) travel;

11 (2) lodging;

12 (3) parking and tolls; and

13 (4) other costs considered appropriate by the
14 organization.

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

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

18 (A) the prospective subject provides informed
19 consent for a cancer clinical trial; or

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

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

26 (3) must provide reimbursement for ancillary costs,
27 including costs described by Section 50.0002, to eliminate the

1 financial barriers to enrollment in a clinical trial;

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

6 (5) must comply with applicable federal and state
7 laws.

8 (b) The independent, third-party organization
9 administering the program shall provide written notice to
10 prospective subjects of the requirements described by Subsection
11 (a).

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

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

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

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

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

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

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

1 Sec. 50.0005. REIMBURSEMENT STATUS AS INDUCEMENT.

2 Reimbursement to a subject of ancillary costs under the program:

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

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

7 (3) is meant to accomplish parity in access to cancer
8 clinical trials and remove barriers to participation in cancer
9 clinical trials for financially burdened subjects.

10 Sec. 50.0006. FUNDING. The independent, third-party
11 organization that administers the program may accept gifts, grants,
12 and donations from any public or private source to implement this
13 chapter.

14 Sec. 50.0007. COLLABORATION. The independent, third-party
15 organization that administers the program may collaborate with the
16 Cancer Prevention and Research Institute of Texas established under
17 Chapter 102 to provide reimbursement under the program.

18 SECTION 3. Section 102.203(b), Health and Safety Code, is
19 amended to read as follows:

20 (b) Except as otherwise provided by this section, money
21 awarded under this subchapter may be used for authorized expenses,
22 including honoraria, salaries and benefits, travel, conference
23 fees and expenses, consumable supplies, other operating expenses,
24 contracted research and development, capital equipment, ~~and~~
25 construction or renovation of state or private facilities, and
26 reimbursement for costs of participation incurred by cancer
27 clinical trial participants, including transportation, lodging,

1 and any costs reimbursed under the cancer clinical trial
2 participation program established under Chapter 50.

3 SECTION 4. This Act takes effect September 1, 2019.