By: Parker H.B. No. 3721

Substitute the following for H.B. No. 3721:

By: Price C.S.H.B. No. 3721

A BILL TO BE ENTITLED

AN ACT

relating to access to and participation in cancer clinical trials.

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

SECTION 1. (a) This Act shall be known as the "Improving Patient Access to Cancer Clinical Trials Act."

(b) The legislature finds that:

(1) the ability to translate medical findings from research to practice relies largely on robust patient participation and a diverse participation pool in cancer clinical trials;

(2) diverse patient participation in cancer clinical trials depends partly on whether a participant is able to afford ancillary costs, including transportation and lodging, during the course of the patient's participation;

(3) significant health disparities exist among socioeconomic, racial, ethnic, and regional groups in this state; and

(4) the health disparities threaten one of the most basic ethical underpinnings of clinical research: the benefits of research must be made available equitably among all eligible individuals.

(c) It is the intent of the legislature to:

(1) provide for a program in this state that encourages greater patient access to cancer clinical trials;

(2) assist patients who are facing financial barriers

that limit their ability to participate in cancer clinical trials and patients who have been identified as a priority for health services in participating in cancer clinical trials by reimbursing the patients for directly incurred expenses;

(3) ensure that cancer clinical trials are widely accessible, improve the development of cancer therapy, and enhance innovation in cancer research and treatment; and

(4) clearly provide that the reimbursement of direct costs incurred by a cancer clinical trial participant or ancillary medical costs incurred by a third party does not constitute coercion or undue influence and instead improves access to cancer clinical trials as supported by the United States Food and Drug Administration's draft guidance "Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors," which provides that the payments made to cancer clinical trial participants are considered reimbursement for expenses and inconveniences and not a benefit of participation.

SECTION 2. Section 102.051(a), Health and Safety Code, is amended to read as follows:

(a) The institute:

(1) may make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and may make grants to institutions of learning and to advanced medical research facilities and collaborations in this state for:

(A) research into the causes of and cures for all types of cancer in humans;

(B) facilities for use in research into the

causes of and cures for cancer;

(C) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans; [~~and~~]

(D) cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans; and

(E) programs designed to encourage access to and participation in cancer clinical trials and associated research and community outreach;

(2) may support institutions of learning and advanced medical research facilities and collaborations in this state in all stages in the process of finding the causes of all types of cancer in humans and developing cures, from laboratory research to clinical trials and including programs to address the problem of access to advanced cancer treatment;

(3) may establish the appropriate standards and oversight bodies to ensure the proper use of funds authorized under this chapter for cancer research and facilities development;

(4) may employ necessary staff to provide administrative support;

(5) shall continuously monitor contracts and agreements authorized by this chapter and ensure that each grant recipient complies with the terms and conditions of the grant contract;

(6) shall ensure that all grant proposals comply with

this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval; and

(7) shall establish procedures to document that the institute, its employees, and its committee members appointed under this chapter comply with all laws and rules governing the peer review process and conflicts of interest.

SECTION 3. The heading to Section 102.155, Health and Safety Code, is amended to read as follows:

Sec. 102.155. AD HOC ADVISORY COMMITTEES [~~COMMITTEE~~].

SECTION 4. Section 102.155(a), Health and Safety Code, is amended to read as follows:

(a) The oversight committee shall create [~~an~~] ad hoc committees [~~committee~~] of experts to address childhood cancers and access to and participation in cancer clinical trials. The oversight committee, as necessary, may create additional ad hoc committees of experts to advise the oversight committee on issues relating to cancer.

SECTION 5. Section 102.203(b), Health and Safety Code, is amended to read as follows:

(b) Except as otherwise provided by this section, money awarded under this subchapter may be used for authorized expenses, including honoraria, salaries and benefits, travel, conference fees and expenses, consumable supplies, other operating expenses, contracted research and development, capital equipment, [~~and~~] construction or renovation of state or private facilities, and reimbursement for costs incurred by cancer clinical trial

participants that are related to the participation, including transportation and lodging.

SECTION 6. This Act takes effect September 1, 2017.