

**BILL ANALYSIS**

C.S.H.B. 3721  
By: Parker  
Public Health  
Committee Report (Substituted)

**BACKGROUND AND PURPOSE**

Interested parties contend that patient participation in cancer clinical trials has suffered due to the high costs associated with involvement. C.S.H.B. 3721 seeks to reduce the costs associated with participation in such trials.

**CRIMINAL JUSTICE IMPACT**

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

**RULEMAKING AUTHORITY**

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

**ANALYSIS**

C.S.H.B. 3721 amends the Health and Safety Code to authorize the Cancer Prevention and Research Institute of Texas (CPRIT) to make grants to institutions of learning and to advanced medical research facilities and collaborations in Texas for programs designed to encourage access to and participation in cancer clinical trials and associated research and community outreach. The bill requires the Cancer Prevention and Research Institute of Texas Oversight Committee to create an ad hoc committee of experts to address access to and participation in cancer clinical trials and includes among the specified purposes for which money awarded from the cancer prevention and research fund or from the issuance of general obligation bonds on behalf of CPRIT reimbursement for costs incurred by cancer clinical trial participants that are related to the participation, including transportation and lodging.

**EFFECTIVE DATE**

September 1, 2017.

**COMPARISON OF ORIGINAL AND SUBSTITUTE**

While C.S.H.B. 3721 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

**INTRODUCED**

**HOUSE COMMITTEE SUBSTITUTE**

SECTION 1. (a) This Act shall be known as the Improve Patient Access to Cancer

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Clinical Trials Act.

- (b) The legislature finds that:
- (1) the ability to translate medical findings from research to practice relies largely on having robust patient participation and a diverse participation pool during cancer clinical trials;
  - (2) diverse patient participation in cancer clinical trial depends, in part, on whether a participant can afford ancillary costs like transportation and lodging during the course of the patient's participation;
  - (3) there are significant health disparities that exist among socioeconomic, racial, ethnic, and regional groups in Texas; and
  - (4) this disparity threatens one of the most basic ethical underpinnings of clinical research, the requirements that the benefits of research be made available equitably among all eligible individuals.
- (c) It is the intent of the legislature to:
- (1) establish a program in the state that encourages greater patient access to cancer clinical trials;
  - (2) assist patients facing financial barriers that inhibit their participation in cancer clinical trials, or assist patients who have been identified as priorities for health services to participate in cancer clinical trials by reimbursing direct patient incurred expenses; and
  - (3) ensure these trials are widely accessible, improve the development of therapies, and enhance innovation.

SECTION 2. Chapter 102.051, Health and Safety Code, is amended to read as follows:  
Sec. 102.051. POWERS AND DUTIES.  
(a) The institute:  
(1) may make grants to provide funds to

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 to encourage access to and participation in 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.

(b) The institute shall work to implement the Texas Cancer Plan and continually

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.

monitor and revise the Texas Cancer Plan as necessary.

(c) The institute shall employ a chief compliance officer to monitor and report to the oversight committee regarding compliance with this chapter and rules adopted under this chapter.

(d) The chief compliance officer shall:

(1) 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

(2) attend and observe the meetings of the program integration committee to ensure compliance with this chapter and rules adopted under this chapter.

No equivalent provision.

SECTION 3. Chapter 102.155, Health and Safety Code, is amended to read as follows:  
Sec. 102.155. AD HOC ADVISORY COMMITTEE.

(a) The oversight committee shall create ~~an~~ ad hoc committees of experts to address issues including childhood cancers and access to 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.

(b) Ad hoc committee members shall serve for a period determined by the oversight committee.

SECTION 4. Chapter 102.203, Health and Safety Code, is amended to read as follows:

Sec. 102.203. AUTHORIZED USE OF FUNDS. (a) A person awarded money from the cancer prevention and research fund or from bond proceeds under this subchapter may use the money for research consistent with the purpose of this chapter and in accordance with a contract between the person and the institute.

(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

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 financial assistance for costs related to participation in clinical trials such as transportation and lodging.

(c) A person receiving money under this subchapter for cancer research may not spend more than five percent of the money for indirect costs. For purposes of this subsection, "indirect costs" means the expenses of doing business that are not readily identified with a particular grant, contract, project, function, or activity, but are necessary for the general operation of the organization or the performance of the organization's activities.

(d) Not more than five percent of the money awarded under this subchapter may be used for facility purchase, construction, remodel, or renovation purposes during any year. Expenditures of money awarded under this subchapter for facility purchase, construction, remodel, or renovation projects must benefit cancer prevention and research.

(e) Not more than 10 percent of the money awarded under this subchapter may be used for cancer prevention and control programs during any year.

SECTION 5. This Act takes effect September 1, 2017.

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. Same as introduced version.