BILL ANALYSIS

Senate Research Center
86R22057 JG-D

H.B. 3147
By: Parker (Creighton)
Health & Human Services
5/16/2019
Engrossed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

During the 85th Legislative Session, H.B. 810, also known as Charlie's Law, which allowed patients with certain severe chronic diseases or terminal illnesses to access adult stem cell treatments, was passed by the legislature and signed into law by the governor.

Interested parties have noted difficulty in accessibility as well as operational issues relative to this statute. H.B. 3148 seeks to address these problems by clarifying that the government cannot prohibit a qualifying individual from receiving adult stem cell treatments unless the adult stem cells to be administered have been deemed to be adulterated or misbranded.

It has also been observed that licensed physicians operating under the United States Food and Drug Administration's (FDA) rules regarding stem cell treatments were affected by the passage of H.B. 3148.

H.B. 3148 seeks to clarify that there are no current laws or rules in existence that would prohibit a licensed physician from utilizing FDA registered, commercially available stem cells for their intended homologous use.

The committee substitute adds language for an investigational stem cell registry with a delayed effective date of the registry and changes the bill's Section 3 reference from the "department" to the "Texas Medical Board."

H.B. 3147 amends current law relating to a cancer clinical trial participation program.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Provides that 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 (FDA) 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 FDA'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. Amends Subtitle B, Title 2, Health and Safety Code, by adding Chapter 50, as follows:

CHAPTER 50. CANCER CLINICAL TRIAL PARTICIPATION PROGRAM

Sec. 50.0001. DEFINITIONS. Defines "cancer clinical trial," "inducement," "program," and "subject" for purposes of this chapter.

Sec. 50.0002. ESTABLISHMENT. Authorizes an independent, third-party organization to 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 certain items.

Sec. 50.0003. REQUIREMENTS; NOTICE. (a) Provides that the program:

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

(4) is authorized to 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) is required to comply with applicable federal and state laws.

(b) Requires the independent, third-party organization administering the program to provide written notice to prospective subjects of the requirements described by Subsection (a).

Sec. 50.0004. REIMBURSEMENT REQUIREMENTS; NOTICE. (a) Requires a reimbursement under the program to:

(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) Provides that 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) Requires the independent, third-party organization operating the program to 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. Provides that 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. Authorizes the independent, third-party organization that administers the program to accept gifts, grants, and donations from any public or private source to implement this chapter.

Sec. 50.0007. COLLABORATION. Authorizes the independent, third-party organization that administers the program to collaborate with the Cancer Prevention and Research Institute of Texas established under Chapter 102 (Cancer Prevention and Research Institute of Texas) to provide reimbursement under the program.

SECTION 3. Amends Section 102.203(b), Health and Safety Code, as follows:

(b) Authorizes money awarded under this subchapter (Cancer Prevention and Research Fund), except as otherwise provided by this section (Authorized Use of Funds), to 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, construction or renovation of state or private facilities, and reimbursement for costs of participation incurred by cancer clinical trial participants, including transportation, lodging, and any costs reimbursed under the cancer clinical trial participation program established under Chapter 50. Makes a nonsubstantive change.

SECTION 4. Effective date: September 1, 2019.