

## **BILL ANALYSIS**

C.S.H.B. 177  
By: Zedler  
State Affairs  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

Interested parties report that human stem cell research is currently being conducted at universities across Texas and point to scholarly publication, testimony from university leaders and scientists, and laboratories where research is occurring as evidence. These parties also report that stem cell research is supported by a variety of funding sources, including federal, state, and local funds, as well as funding from nonprofit and private for-profit entities. In order to further adult stem cell research through a variety of activities and to address the collection and use of adult stem cells, C.S.H.B. 177 seeks to create the Texas Adult Stem Cell Research Coordinating Board.

### **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. 177 amends the Education Code to establish the seven-member Texas Adult Stem Cell Research Coordinating Board, which is composed of three members appointed by the governor, two members appointed by the lieutenant governor, and two members appointed by the speaker of the house of representatives. The bill sets out provisions relating to board member terms, the designation of a presiding officer, and the procedure for filling a vacancy. The bill specifies certain conflicts of interest that preclude a person from being a member of the research coordinating board. The bill provides for the staggering of the initial members' terms.

C.S.H.B. 177 requires the research coordinating board to establish the Texas Adult Stem Cell Research Consortium, which is composed of participating institutions of higher education and businesses that accept public money for adult stem cell research or otherwise agree to participate in the consortium. The bill requires the research coordinating board to administer the adult stem cell research program to make grants and loans to consortium members for adult stem cell research projects, the development of facilities to be used solely for such projects, and the commercialization of products or technology involving adult stem cell research and treatments; to support consortium members in all stages of the process of developing treatments and cures based on adult stem cell research; to establish appropriate regulatory standards and oversight bodies for adult stem cell research conducted by consortium members and the development of facilities for consortium members conducting adult stem cell research; and to assist consortium members in applying for grants or loans under the program. The bill requires the research coordinating board to develop research priorities, guidelines, and procedures for providing grants

and loans that are made on a competitive, peer review basis for specific research projects conducted by the consortium members. The bill requires the consortium to solicit, and authorizes the research coordinating board to accept on behalf of the consortium, a gift, grant, or donation made from any public or private source for the purpose of promoting adult stem cell research or commercialization. The bill requires the adult stem cell research program to be funded by such gifts, grants, and donations and prohibits funding of the program by legislative appropriations.

C.S.H.B. 177 requires the research coordinating board, not later than September 1 of each even-numbered year starting with 2016, to submit a report of the board's activities and recommendations to the Texas Higher Education Coordinating Board and to the governor, the lieutenant governor, the speaker of the house of representatives, and the presiding officer of each legislative standing committee or subcommittee with jurisdiction over higher education.

C.S.H.B. 177 amends the Health and Safety Code to authorize blood obtained by a blood bank to be used for the collection of adult stem cells if the donor consents in writing to that use. The bill requires a person using adult stem cells in the provision of health care to use adult stem cells that are properly manufactured and stored and authorizes such a person to only use adult stem cells in a clinical trial approved by the United States Food and Drug Administration (FDA). The bill authorizes a hospital to use adult stem cells in a procedure if a physician providing services at the hospital determines that the use of adult stem cells in the procedure is appropriate, the patient consents in writing to the use, the bill's requirements for stem cell use are met, the manufacturing processes for the adult stem cells satisfy current good manufacturing practices adopted by the FDA, and appropriate state and federal guidelines on the use of adult stem cells are followed.

#### **EFFECTIVE DATE**

September 1, 2015.

#### **COMPARISON OF ORIGINAL AND SUBSTITUTE**

While C.S.H.B. 177 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

SECTION 1. Subtitle H, Title 3, Education Code, is amended by adding Chapter 156 to read as follows:

#### CHAPTER 156. ADULT STEM CELL RESEARCH PROGRAM

##### Sec. 156.001. DEFINITIONS.

##### Sec. 156.002. COMPOSITION OF RESEARCH COORDINATING BOARD.

(a) The Texas Adult Stem Cell Research Coordinating Board is composed of seven members appointed as follows:

(1) three members who are interested persons, including at least one person who represents an institution of higher education, appointed by the governor;

(2) two members who are interested persons appointed by the lieutenant

##### HOUSE COMMITTEE SUBSTITUTE

SECTION 1. Subtitle H, Title 3, Education Code, is amended by adding Chapter 156 to read as follows:

#### CHAPTER 156. ADULT STEM CELL RESEARCH PROGRAM

##### Sec. 156.001. DEFINITIONS.

##### Sec. 156.002. COMPOSITION OF RESEARCH COORDINATING BOARD.

(a) The Texas Adult Stem Cell Research Coordinating Board is composed of seven members appointed as follows:

(1) three members who are interested persons, including at least one person who represents an institution of higher education and one person who is a representative of an advocacy organization representing patients, appointed by the governor;

(2) two members who are interested persons appointed by the lieutenant

governor; and

(3) two members who are interested persons appointed by the speaker of the house of representatives.

(b) The governor shall designate as the presiding officer of the research coordinating board a board member appointed under Subsection (a)(1) who represents an institution of higher education. The presiding officer serves in that capacity at the will of the governor.

(c) The members of the research coordinating board serve staggered six-year terms. If a vacancy occurs on the board, the appropriate appointing authority shall appoint, in the same manner as the original appointment, another person to serve for the remainder of the unexpired term.

Sec. 156.003. CONFLICT OF INTEREST.

Sec. 156.004. COMPOSITION OF CONSORTIUM.

Sec. 156.005. ADMINISTRATION OF PROGRAM; GUIDELINES AND PROCEDURES.

Sec. 156.006. FUNDING.

Sec. 156.007. GIFTS, GRANTS, AND DONATIONS.

Sec. 156.008. BIENNIAL REPORT.

SECTION 2. Section 162.001, Health and Safety Code, is amended.

SECTION 3. Chapter 162, Health and Safety Code, is amended.

SECTION 4. Section 241.003, Health and Safety Code, is amended by amending Subdivision (1) and adding Subdivision (1-a) to read as follows:

(1) "Adult stem cell" has the meaning assigned by Section 162.001.

(1-a) "Advanced practice nurse" means a registered nurse recognized as an advanced practice nurse by the Texas Board of Nursing.

No equivalent provision.

governor; and

(3) two members who are interested persons appointed by the speaker of the house of representatives.

(b) The governor shall designate as the presiding officer of the research coordinating board a board member appointed under Subsection (a)(1) who represents an institution of higher education. The presiding officer serves in that capacity at the will of the governor.

(c) The members of the research coordinating board serve staggered six-year terms. If a vacancy occurs on the board, the appropriate appointing authority shall appoint, in the same manner as the original appointment, another person to serve for the remainder of the unexpired term.

Sec. 156.003. CONFLICT OF INTEREST.

Sec. 156.004. COMPOSITION OF CONSORTIUM.

Sec. 156.005. ADMINISTRATION OF PROGRAM; GUIDELINES AND PROCEDURES.

Sec. 156.006. FUNDING.

Sec. 156.007. GIFTS, GRANTS, AND DONATIONS.

Sec. 156.008. BIENNIAL REPORT.

SECTION 2. Same as introduced version.

SECTION 3. Same as introduced version.

No equivalent provision.

SECTION 4. The heading to Chapter 1003, Health and Safety Code, is amended to read as follows:

~~CHAPTER 1003. [AUTOLOGOUS STEM CELL BANK FOR RECIPIENTS OF~~

~~BLOOD AND TISSUE COMPONENTS WHO ARE THE LIVE HUMAN DONORS OF THE] ADULT STEM CELLS~~

SECTION 5. Subchapter A, Chapter 241, Health and Safety Code, is amended by adding Section 241.010 to read as follows:

Sec. 241.010. USE OF ADULT STEM CELLS. A hospital may use adult stem cells in a procedure if a physician providing services at the hospital determines that the use of adult stem cells in the procedure is appropriate and the patient consents in writing to the use.

SECTION 6. (a) As soon as practicable after the effective date of this Act, the governor, lieutenant governor, and speaker of the house of representatives shall appoint members to the Texas Adult Stem Cell Research Coordinating Board, as required by Section 156.002, Education Code, as added by this Act, as follows:

- (1) the governor shall appoint one member to a term expiring February 1, 2017, one member to a term expiring February 1, 2019, and one member to a term expiring February 1, 2021;
- (2) the lieutenant governor shall appoint one member to a term expiring February 1, 2019, and one member to a term expiring February 1, 2021; and

SECTION 5. Chapter 1003, Health and Safety Code, is amended by adding Sections 1003.002 and 1003.003 to read as follows:

Sec. 1003.002. GENERAL REQUIREMENTS FOR ADULT STEM CELL USE IN HEALTH CARE. A person using adult stem cells in the provision of health care:

- (1) must use adult stem cells that are properly manufactured and stored; and
- (2) may only use adult stem cells in a clinical trial approved by the United States Food and Drug Administration.

Sec. 1003.003. ADDITIONAL REQUIREMENTS FOR ADULT STEM CELL USE IN HOSPITALS. A hospital may use adult stem cells in a procedure if:

- (1) a physician providing services at the hospital determines that the use of adult stem cells in the procedure is appropriate;
- (2) the patient consents in writing to the use;
- (3) the requirements for stem cell use under Section 1003.002 are met;
- (4) the manufacturing processes for the adult stem cells satisfy current good manufacturing practices adopted by the United States Food and Drug Administration; and
- (5) appropriate state and federal guidelines on the use of adult stem cells are followed.

SECTION 6. Same as introduced version.

(3) the speaker of the house of representatives shall appoint one member to a term expiring February 1, 2019, and one member to a term expiring February 1, 2021.

(b) Not later than September 1, 2016, the Texas Adult Stem Cell Research Coordinating Board shall submit the first report of the board's activities and recommendations as required by Chapter 156, Education Code, as added by this Act.

SECTION 7. This Act takes effect September 1, 2015.

SECTION 7. Same as introduced version.