BILL ANALYSIS

Senate Research Center 84R14977 SCL-D H.B. 177 By: Zedler et al. (Bettencourt) Health & Human Services 5/19/2015 Engrossed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Interested parties report that human stem cell research is currently being conducted at universities across Texas and point to scholarly publications, 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, H.B. 177 seeks to create the Texas Adult Stem Cell Research Coordinating Board.

H.B. 177 amends current law relating to the research, collection, and use of adult stem cells.

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. Amends Subtitle H, Title 3, Education Code, by adding Chapter 156, as follows:

CHAPTER 156. ADULT STEM CELL RESEARCH PROGRAM

Sec. 156.001. DEFINITIONS. Defines "adult stem cell," "consortium," "institution of higher education," "program," and "research coordinating board" in this chapter.

Sec. 156.002. COMPOSITION OF RESEARCH COORDINATING BOARD. (a) Provides that 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) Requires the governor to 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. Provides that the presiding officer serves in that capacity at the will of the governor.
- (c) Provides that the members of the research coordinating board serve staggered six-year terms. Requires the appropriate appointing authority, if a vacancy occurs

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on the board, to 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. (a) Defines "Texas trade association" in this section.

- (b) Prohibits a person from being a member of the research coordinating board if:
 - (1) the person is an officer, employee, or paid consultant of a Texas trade association in the field of medicine;
 - (2) the person's spouse is an officer, manager, or paid consultant of a Texas trade association in the field of medicine; or
 - (3) the person is a member of the Texas Higher Education Coordinating Board (THECB).
- (c) Prohibits a person from being a member of the research coordinating board if the person is required to register as a lobbyist under Chapter 305 (Registration of Lobbyists), Government Code, because of the person's activities for compensation on behalf of a profession related to the operation of the board.

Sec. 156.004. COMPOSITION OF CONSORTIUM. (a) Requires the research coordinating board to establish the Texas Adult Stem Cell Research Consortium.

- (b) Provides that the consortium is composed of participating institutions of higher education and businesses that:
 - (1) accept public money for adult stem cell research; or
 - (2) otherwise agree to participate in the consortium.

Sec. 156.005. ADMINISTRATION OF PROGRAM; GUIDELINES AND PROCEDURES. (a) Requires the research coordinating board to administer the program to:

- (1) make grants and loans to consortium members for:
 - (A) adult stem cell research projects, including projects to develop therapies, protocols, or medical procedures involving adult stem cells;
 - (B) the development of facilities to be used solely for adult stem cell research projects; and
 - (C) the commercialization of products or technology involving adult stem cell research and treatments;
- (2) support consortium members in all stages of the process of developing treatments and cures based on adult stem cell research, beginning with initial laboratory research through successful clinical trials;
- (3) establish appropriate regulatory standards and oversight bodies for:
 - (A) adult stem cell research conducted by consortium members; and
 - (B) the development of facilities for consortium members conducting adult stem cell research; and

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- (4) assist consortium members in applying for grants or loans under the program.
- (b) Requires the research coordinating board to develop research priorities, guidelines, and procedures for providing grants and loans for specific research projects conducted by consortium members. Requires that the priorities, guidelines, and procedures require the grants and loans to be made on a competitive, peer review basis.

Sec. 156.006. FUNDING. Requires the program to be funded by gifts, grants, and donations described by Section 156.007. Prohibits the program from being funded by legislative appropriations.

Sec. 156.007. GIFTS, GRANTS, AND DONATIONS. Requires the consortium to solicit, and the research coordinating board may 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.

Sec. 156.008. BIENNIAL REPORT. Requires the research coordinating board, not later than September 1 of each even-numbered year, to submit a report of the board's activities and recommendations to THECB 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.

SECTION 2. Amends Section 162.001, Health and Safety Code, by adding Subdivision (4) to define "adult stem cell."

SECTION 3. Amends Chapter 162, Health and Safety Code, by adding Section 162.020, as follows:

Sec. 162.020. ADULT STEM CELL COLLECTION. Authorizes 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.

SECTION 4. Amends the heading to Chapter 1003, Health and Safety Code, to read as follows:

CHAPTER 1003. ADULT STEM CELLS

SECTION 5. Amends Chapter 1003, Health and Safety Code, by adding Sections 1003.002 and 1003.003, as follows:

Sec. 1003.002. GENERAL REQUIREMENTS FOR ADULT STEM CELL USE IN HEALTH CARE. Provides that 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. Authorizes a hospital to 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;

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- (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. (a) Requires the governor, lieutenant governor, and speaker of the house of representatives, as soon as practicable after the effective date of this Act, to 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 is required to 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 is required to appoint one member to a term expiring February 1, 2019, and one member to a term expiring February 1, 2021; and
 - (3) the speaker of the house of representatives is required to appoint one member to a term expiring February 1, 2019, and one member to a term expiring February 1, 2021.
 - (b) Requires the Texas Adult Stem Cell Research Coordinating Board, not later than September 1, 2016, to 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. Effective date: September 1, 2015.

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