BILL ANALYSIS

C.S.H.B. 3148
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

It has been suggested that more patients with certain severe chronic diseases or terminal illnesses should be able to access adult stem cell treatments. C.S.H.B. 3148 seeks to address this issue by setting out provisions relating to the administration and oversight of investigational adult stem cell treatments administered to certain patients.

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. 3148 amends the Health and Safety Code to require the Department of State Health Services (DSHS) to administer provisions relating to the provision of investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses. The bill replaces the authorization for the executive commissioner of the Health and Human Services Commission (HHSC) by rule to adopt a form for informed consent to receive an investigational stem cell treatment with a requirement for the executive commissioner by rule to do so. The bill requires the form to provide notice that DSHS administers such provisions. The bill requires an institutional review board that oversees investigational stem cell treatments to meet one of the following conditions, among others:

- be accredited by the Association for the Accreditation of Human Research Protection Programs;
- be registered by the U.S. Department of Health and Human Services, Office for Human Research Protections, in accordance with federal regulations; or
- be accredited by a national accreditation organization acceptable to DSHS.

C.S.H.B. 3148 prohibits a governmental entity or an officer, employee, or agent of a governmental entity from interfering with an eligible patient's access to or use of an investigational stem cell treatment, unless the treatment uses an adult stem cell product that is considered an adulterated or misbranded drug. The bill prohibits a governmental entity from considering the adult stem cell product to be an adulterated or misbranded drug solely on the basis that the U.S. Food and Drug Administration (FDA) has not approved the adult stem cell product.

C.S.H.B. 3148 prohibits its provisions relating to the provision of investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses from being construed to prohibit a physician from using adult stem cells for their intended homologous use if the stem cells are produced by a manufacturer registered by the FDA and commercially available or to require an institutional review board to oversee treatment using adult stem cells registered by the FDA for their intended homologous use.

EFFECTIVE DATE

September 1, 2019.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 3148 may differ from the original in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

The substitute includes a provision replacing the authorization for the executive commissioner of HHSC by rule to adopt a form for informed consent with a requirement that the executive commissioner by rule do so.

The substitute requires the form to provide notice that DSHS administers provisions relating to the provision of investigational stem cell treatment to certain patients.

The substitute includes a specification that the prohibition against a governmental entity or an employee, officer, or agent of a governmental entity interfering with an eligible patient's access to or use of a stem cell treatment applies to an investigational stem cell treatment. The substitute specifies that a treatment using an adult stem cell product is excepted from that prohibition if it is considered an adulterated or misbranded drug.

The substitute changes a reference to stem cells registered by the FDA to refer instead to stem cells produced by a manufacturer registered by the FDA for purposes of laying out the construction of its provisions.