SUBJECT: Requiring DSHS to administer investigational adult stem cell treatments

COMMITTEE: Public Health — committee substitute recommended

VOTE: 10 ayes — S. Thompson, Wray, Allison, Coleman, Frank, Guerra, Ortega, Price, Sheffield, Zedler

0 nays

1 absent — Lucio

WITNESSES: For — Michelle Wittenburg, KK125 Ovarian Cancer Research Foundation; Tracy Thompson and Jennifer Ziegler, Patients For Stem Cells; (*Registered, but did not testify*: Carmen Cernosek; Rick Hardcastle)

Against — Mary Pat Moyer, InCell; David Bales, Texans for Cures

On — Sheila Hemphill, Texas Right To Know; (*Registered, but did not testify*: Manda Hall and Barbara Klein, Department of State Health Services)

BACKGROUND: Health and Safety Code ch. 1003, subch. B allows patients with certain severe chronic diseases or terminal illnesses to use investigational adult stem cell treatment, which is a treatment in a clinical trial and that has not yet been approved for general use by the U.S. Food and Drug Administration. Sec. 1003.055(d) requires an institutional review board that oversees investigational stem cell treatments to be affiliated with a medical school in Texas or a licensed hospital that has at least 150 beds.

Sec. 1003.058 prohibits a governmental entity or its employee from interfering with an eligible patient's access to or use of an authorized stem cell treatment.

Sec. 1003.054(c) allows the executive commissioner of the Health and Human Services Commission by rule to adopt an informed consent form required to be signed by eligible patients before receiving investigational

stem cell treatment.

DIGEST:

CSHB 3148 would require the Department of State Health Services (DSHS) to oversee the provision of investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses.

The bill would require an institutional review board to meet one of the following conditions:

- be affiliated with a medical school in Texas or licensed hospital with at least 150 beds;
- 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; or
- be accredited by a national accreditation organization acceptable to DSHS.

Unless the patient's treatment used an adult stem cell product that was considered an adulterated or misbranded drug, the bill would prohibit a governmental entity or its employee from interfering with an eligible patient's access to or use of an authorized investigational stem cell treatment.

The bill would require the executive commissioner of the Health and Human Services Commission by rule to adopt an informed consent form required to be signed by eligible patients before receiving investigational stem cell treatment. The form would have to provide notice that DSHS would be governing the provision of investigational stem cell treatments.

The bill's provisions could not be construed to prohibit a physician from using adult stem cells for their intended homologous use if the stem cells were produced by a registered U.S. Food and Drug Administration (FDA) manufacturer and commercially available. The bill's provisions also could not be construed to require an institutional review board to oversee treatment using adult stem cells registered by the FDA for their intended

homologous use.

The bill would take effect September 1, 2019.

SUPPORTERS SAY:

CSHB 3148 would clarify existing law for patients and providers regarding investigational stem cell treatment. The bill would improve patient safety by allowing a governmental entity to interfere with the treatment if the treatment used an adult stem cell product considered to be adulterated or misbranded under the Texas Food, Drug, and Cosmetic Act. Expanding the list of affiliated institutional review boards that could oversee investigational stem cell treatments would increase patients' access to these lifesaving treatments. The institutional review boards would still be required to comply with the Texas Medical Board's adopted rules.

OPPONENTS SAY:

CSHB 3148 could create more confusion about stem cell treatment terminology for patients and providers. Expanding the list of authorized institutional review boards could make it more difficult to regulate fraudulent clinics providing expensive or unauthorized treatments for patients, increasing potential harm to patients. The Texas Medical Board, rather than the Department of State Health Services, would be the more appropriate agency to oversee investigational stem cell treatment.