SUBJECT: Allowing patients with chronic diseases to access investigational drugs

COMMITTEE: Public Health — committee substitute recommended

VOTE: 11 ayes — Price, Sheffield, Arévalo, Burkett, Coleman, Collier, Cortez, Guerra, Klick, Oliverson, Zedler

0 nays

WITNESSES: For — Mary Martin, Jennifer Perez; Beverly Kotsanis, Kotsanis Institute; Sheila Hemphill, Texas Right To Know; Rickie Martin; Dorothy Paredes; Karen Sloan; (*Registered, but did not testify*: Rick Hardcastle, Celltex Therapeutics; V.A. Stephens, Michelle Wittenburg, and Adam Jones, KK125 Foundation; Coleman Hemphill, Texas Right To Know; and 13 individuals)

Against — None

On — David Bales, Texans for Cures; (*Registered, but did not testify*: Jonathan Huss, Department of State Health Services; Doug Danzeiser, Texas Department of Insurance; Robert Bredt, Scott Freshour, and Monique Johnston, Texas Medical Board)

BACKGROUND: In 2015, the 84th Legislature enacted HB 21 by Kacal, the "Right to Try Act," to allow patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices in clinical trials.

Certain individuals maintain that the Right to Try Act should be expanded to allow patients who are diagnosed with certain severe chronic diseases to access the same investigational treatments as the terminally ill.

DIGEST: CSHB 661 would allow a patient to be eligible to access and use an investigational drug, biological product, or device if the patient had a severe chronic disease, as attested by a physician, and the patient's physician:

- considered all other treatment options in consultation with the patient;
- determined other treatment options unavailable or unlikely to provide relief; and
- recommended or prescribed in writing that the patient use a specific class of investigational drug, biological product, or device.

The bill would define "investigational drug, biological product, or device" as a drug, product, or device that successfully completed phase one of a clinical trial but has not been approved for general use by the United States Food and Drug Administration (FDA) or its international equivalent.

The bill would define "severe chronic disease" as a condition, illness, or injury that lasts for at least one year, requires ongoing medical attention, and entails significant functional impairment or severe pain that limits a person's activities of daily life.

An eligible patient, or the patient's parent, guardian or conservator, would have to provide written informed consent before receiving an investigational drug.

The bill would not create a private or state cause of action against the manufacturer of an investigational drug or other related entity.

An official, employee, or agent of the state could not block or attempt to block an eligible patient's access to an investigational drug.

The Texas Medical Board could not revoke, fail to renew, suspend, or take any action against a physician's license based solely on a recommendation to an eligible patient regarding access to an investigational drug.

The executive commissioner of the Health and Human Services Commission would adopt rules to designate the medical conditions considered severe chronic diseases as soon as practicable after the effective of date of this bill.

The bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2017.