SUBJECT: Allowing the provision of certain individualized investigational treatments

COMMITTEE: Public Health — favorable, without amendment

VOTE: 8 ayes — Klick, Campos, Jetton, J. Jones, V. Jones, Oliverson, Price, Smith

0 nays

3 absent — Collier, A. Johnson, Tinderholt

WITNESSES: For — Naomi Lopez, Goldwater Institute; Hannah Lowe, L-CMD Research Foundation; Sarah Lindley Bailey; Kimberly Moyers (*Registered, but did not testify*: Samuel Sheetz, Americans for Prosperity; Michelle Wittenburg, KK125 Ovarian Cancer Research Foundation; Maureen Milligan, Teaching Hospitals of Texas; Jorge Martinez, The LIBRE Initiative; Maxcine Tomlinson, TX New Mexico Hospice Organization; Michelle Evans)

Against — David Bales, Texans for Cures

BACKGROUND: Concerns have been raised that patients with ultra-rare diseases are not able to access certain individualized investigational treatments that have not completed an FDA-approved phase 1 clinical trial.

DIGEST: HB 4059 would define "individualized investigational treatment" as a drug, biological treatment, or device that was unique to and produced exclusively for an individual patient's use based on the patient's genetic profile.

Eligibility. A health care facility would be eligible to provide an individualized investigational treatment if the facility was operating under federal assurance laws and regulations for the protection of human subjects.

A patient would be eligible to receive an individualized investigational

treatment if the patient had a life-threatening illness or severely debilitating illness that would cause major irreversible morbidity, had considered all other treatment options currently approved by the US Food and Drug Administration, and had given written informed consent. Additionally, the patient's physician would be required to attest to the patient's life-threatening illness or severely debilitating illness and that the patient met requirements under the bill and would have to recommend an individualized investigational treatment based on the patient's genomic sequence, chromosomes, DNA, and certain other characteristics.

Informed consent. The bill would require that informed consent be attested to in writing by the patient's physician and a witness. At a minimum, informed consent would be required to include descriptions of currently approved treatments for the patient's condition and the proposed treatment and possible outcomes, an attestation that the patient agreed with the physician that conventional treatments were unlikely to prolong the patient's life, information related to payment and liability, and a statement related to hospice care eligibility.

If the patient was a minor or lacked the mental capacity to provide informed consent, a parent, legal guardian, managing conservator, or patient's agent could provide written informed consent on the patient's behalf.

Provision of treatment. A patient could request an individualized investigational treatment from a eligible health care facility or manufacturer, and a manufacturer operating within an eligible health care facility and in compliance with all applicable federal assurance laws and regulations could make such a treatment available.

An eligible health care facility or manufacturer could provide an individualized investigational treatment to an eligible patient without receiving compensation or require an eligible patient to pay the costs to manufacture the individualized investigational treatment.

An officer, employee, or agent of the state could not block or attempt to

block an eligible patient's access to an individualized investigational treatment. Counseling, advice, or recommendations consistent with medical standards of care from a licensed health care provider would not violate this provision.

Health coverage. The bill would not affect coverage an insurer was required to provide under the Insurance Code or health care coverage of enrollees in clinical trials. The bill also would not require a governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational treatment. Hospitals and health care facilities would not be required to provide new or additional services unless approved by the facility.

A health benefit plan issuer, third-party administrator, or governmental agency could provide coverage for the cost of an individualized investigational treatment or related costs.

Limiting debt liability and causes of action. If a patient died while being treated with an individualized investigational treatment, the patient's heirs would not be liable for any outstanding debt related to the treatment or lack of health care coverage due to the treatment.

The bill would not create a private cause of action against any person involved in the care of an eligible patient using an individualized investigational treatment for any harm resulting from the treatment if the person was complying in good faith and exercised reasonable care.

Action against licenses or certifications. A state licensing board could not revoke, fail to renew, suspend, or take any action against a health care provider's license based solely on a recommendation to an eligible patient regarding individualized investigational treatments. The Health and Human Services Commission could not take action against a provider's Medicare certification based solely on a recommendation that a patient have access to an individualized investigational treatment.

The bill would take effect September 1, 2023.