BILL ANALYSIS

H.B. 4059
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Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

In 2015, Texas enacted Right to Try to allow terminally ill patients access to investigational treatments that have completed an FDA-approved phase 1 clinical trial. Since then, Right to Try has become federal law. However, for patients with rare or ultra-rare diseases whose treatments are increasingly designed for an individual patient using their own genetics, the existing pathway is not broad enough. Oftentimes, for rare and ultra-rare diseases, there are not clinical trials because there are not enough patients or sufficient commercial viability to support them. H.B. 4059 seeks to extend the benefits of the original Right to Try by establishing a pathway by which patients with rare or ultra-rare diseases may seek, under their doctor's care, personalized treatments developed in federally approved facilities and by providing for patient protections such as informed consent and treatment risk disclosure.

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

Access to Individualized Investigational Treatments

H.B. 4059 amends the Health and Safety Code to make a health care facility eligible to provide an individualized investigational treatment if the facility is operating under a federal assurance for the protection of human subjects under applicable federal laws and regulations and is subject to the federal assurance laws, regulations, policies, and guidelines and renewals or updates to the laws, regulations, policies, and guidelines. The bill establishes the following eligibility criteria for a patient to receive an individualized investigational treatment:

- the patient has a life-threatening illness or severely debilitating illness, has considered all other treatment options currently approved by FDA, and has given written informed consent for the use of the individualized investigational treatment; and
- the patient's physician does the following:
    - attests to the patient's life-threatening illness or severely debilitating illness and that the patient meets the requirements under this section; and
    - recommends an individualized investigational treatment for the patient based on analysis of the patient's genomic sequence, human chromosomes, DNA, RNA, genes, gene products such as enzymes and other types of proteins, or metabolites.

The bill prohibits an eligible patient from receiving an individualized investigational treatment unless the patient provides written informed consent. If the patient is a minor or lacks the mental

capacity to provide informed consent, a parent, legal guardian, managing conservator, or patient's agent, may provide written informed consent on the patient's behalf.

H.B. 4059 requires informed consent for purposes of access to individualized investigational treatment to be attested to in writing by the patient's physician and a witness and to include at a minimum the following information:

- an explanation of the currently approved products and treatments for the patient's disease or condition;
- an attestation that the patient concurs with the patient's physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;
- clear identification of the specific proposed individualized investigational drug, biological product, or device the patient's physician recommends;
- a description, based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's disease or condition, of the potentially best and worst outcomes of using the individualized investigational treatment, and of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment;
- a statement that the patient's health benefit plan issuer or third-party administrator and provider are not obligated to pay the cost of any care or treatments related to the use of the individualized investigational treatment unless payment is specifically required by law or contract;
- a statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the individualized investigational treatment and that care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements; and
- a statement that the patient understands the patient is liable for all expenses related to the use of the individualized investigational treatment and the liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the treatment states otherwise.

H.B. 4059, with respect to the provision of an individualized investigative treatment, does the following:

- authorizes a manufacturer operating within an eligible health care facility and in compliance with all applicable federal assurance laws and regulations to make the treatment available;
- authorizes an eligible patient to request to receive the treatment from an eligible health care facility or manufacturer operating within an eligible health care facility;
- establishes that a manufacturer is not required to make the treatment available to an eligible patient; and
- authorizes an eligible health care facility or such a manufacturer to provide the treatment to an eligible patient without receiving compensation or to require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the treatment.

If a patient dies while being treated under an individualized investigational treatment, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of health coverage due to the treatment.

H.B. 4059 expressly does not create a private cause of action against a manufacturer of an individualized investigational treatment or against any other person involved in the care of an eligible patient using the treatment for any harm to the eligible patient resulting from the treatment if the manufacturer or other person is complying in good faith with the terms of these bill provisions and has exercised reasonable care.

H.B. 4059 prohibits an officer, employee, or agent of the state from blocking or attempting to block an eligible patient's access to an individualized investigational treatment that complies with the bill's provisions and rules adopted under those provisions. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this prohibition.

Health Coverage and Services

H.B. 4059 establishes that the bill's provisions expressly do not:

- affect the coverage required of an insurer under the Insurance Code or health care coverage for routine patient care costs for enrollees in certain clinical trials;
- require a governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational treatment; and
- require a state licensed hospital or health care facility to provide new or additional services unless approved by the hospital or facility.

A health benefit plan issuer, third-party administrator, or governmental agency may, but is not required to, provide coverage for the cost of an individualized investigational treatment or the cost of services related to the use of the treatment under the bill's provisions.

Health Care Providers

H.B. 4059 prohibits a state licensing board from revoking, failing to renew, suspending, or taking any action against a health care provider's license based solely on the health care provider's recommendation to an eligible patient regarding access to or treatment with an individualized investigational treatment. The bill prohibits the Health and Human Services Commission from taking action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an individualized investigational treatment.

Definitions

H.B. 4059 defines the following terms:

- "individualized investigational treatment" as a drug, biological product, or device that is unique to and produced exclusively for use by an individual patient, based on the patient's genetic profile, including individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines;
- "life-threatening illness" means a disease or condition with a significantly increased likelihood of death unless the course of the disease or condition is interrupted or with potentially fatal outcomes and for which the goal of clinical trials is survival; and
- "severely debilitating illness" means a disease or condition that causes major irreversible morbidity.

EFFECTIVE DATE

September 1, 2023.