By: Harrison H.B. No. 4348

A BILL TO BE ENTITLED

AN ACT

relating to the right to try cutting-edge treatments for patients with life-threatening or severely debilitating illnesses.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Title 6, Health and Safety Code, is amended by adding Subtitle C-1 to read as follows:

SUBTITLE C-1. INVESTIGATIONAL TREATMENTS

CHAPTER 491. ACCESS TO INDIVIDUALIZED INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESSES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 491.001. DEFINITIONS. In this chapter:

(1) "Individualized investigational treatment" means 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. The term includes individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.

(2) "Life-threatening illness" means a disease or condition with:

(A) a significantly increased likelihood of death unless the course of the disease or condition is interrupted; or

(B) potentially fatal outcomes and for which the

goal of clinical trials is survival.

(3) "Severely debilitating illness" means a disease or condition that causes major irreversible morbidity.

SUBCHAPTER B. ACCESS TO INDIVIDUALIZED INVESTIGATIONAL TREATMENT

Sec. 491.051. HEALTH CARE FACILITY ELIGIBILITY. A health care facility is eligible to provide an individualized investigational treatment under this chapter if the facility is operating under a federal assurance for the protection of human subjects under 42 U.S.C. Section 289(a) and 45 C.F.R. Part 46 and is subject to the federal assurance laws, regulations, policies, and guidelines and renewals or updates to the laws, regulations, policies, and guidelines.

Sec. 491.052. PATIENT ELIGIBILITY. A patient is eligible to receive an individualized investigational treatment under this chapter if:

(1) the patient:

(A) has a life-threatening illness or severely debilitating illness;

(B) has considered all other treatment options currently approved by the United States Food and Drug Administration; and

(C) has given written informed consent for the use of the individualized investigational treatment; and

(2) the patient's physician:

(A) attests to the patient's life-threatening illness or severely debilitating illness and that the patient meets the requirements under this section; and

(B) recommends an individualized investigational treatment for the patient based on analysis of the patient's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products such as enzymes and other types of proteins, or metabolites.

Sec. 491.053. INFORMED CONSENT. (a) An eligible patient may not receive 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 as defined by Section 166.151 may provide written informed consent on the patient's behalf.

(b) Informed consent under this chapter must be attested to in writing by the patient's physician and a witness.

(c) Informed consent under this chapter must include at a minimum:

(1) an explanation of the currently approved products and treatments for the patient's disease or condition;

(2) 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;

(3) clear identification of the specific proposed individualized investigational drug, biological product, or device the patient's physician recommends;

(4) 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;

(5) 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;

(6) 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

(7) 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 individualized investigational treatment states otherwise.

Sec. 491.054. PROVISION OF TREATMENT; COSTS. (a) A manufacturer operating within an eligible health care facility and in compliance with all applicable federal assurance laws and regulations may make available an individualized investigative treatment, and an eligible patient may request to receive an individualized investigational treatment from an eligible health

care facility or manufacturer operating within an eligible health care facility under this chapter.

(b) A manufacturer is not required under this chapter to make available an individualized investigational treatment to an eligible patient.

(c) An eligible health care facility or manufacturer operating within an eligible health care facility may:

(1) provide an individualized investigational treatment to an eligible patient without receiving compensation; or

(2) require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the individualized investigational treatment.

Sec. 491.055. DEBT LIABILITY ON DEATH OF PATIENT. 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.

Sec. 491.056. NO PRIVATE CAUSE OF ACTION. This chapter 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 individualized investigational treatment for any harm to the eligible patient resulting from the individualized investigational treatment if the manufacturer or other person is complying in good faith with the terms of this chapter and has exercised reasonable care.

Sec. 491.057. STATE MAY NOT INTERFERE WITH ACCESS TO

TREATMENT. (a) An officer, employee, or agent of this state may not block or attempt to block an eligible patient's access to an individualized investigational treatment that complies with this chapter and rules adopted under this chapter.

(b) Notwithstanding Subsection (a), counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

SUBCHAPTER C. HEALTH COVERAGE AND SERVICES

Sec. 491.101. HEALTH COVERAGE. This chapter does not affect:

(1) the coverage required of an insurer under the Insurance Code; or

(2) health care coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

Sec. 491.102. GOVERNMENTAL AGENCY NOT RESPONSIBLE FOR COSTS. This chapter does not require a governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational treatment.

Sec. 491.103. HOSPITAL SERVICES. This chapter does not require a hospital or health care facility licensed under Subtitle B, Title 4, to provide new or additional services unless approved by the hospital or facility.

Sec. 491.104. COVERAGE OPTIONAL. 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 an individualized investigational treatment

under this chapter.

SUBCHAPTER D. HEALTH CARE PROVIDERS

Sec. 491.151. PROHIBITED ACTION AGAINST LICENSE OR CERTIFICATION HOLDER. (a) A state licensing board may not revoke, fail to renew, suspend, or take any action against a health care provider's license issued under Title 3, Occupations Code, based solely on the health care provider's recommendation to an eligible patient regarding access to or treatment with an individualized investigational treatment.

(b) The Health and Human Services Commission may not take 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.

SECTION 2. This Act takes effect September 1, 2023.