

By: King of Hemphill

H.B. No. 4059

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

1 goal of clinical trials is survival.

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

4 SUBCHAPTER B. ACCESS TO INDIVIDUALIZED INVESTIGATIONAL TREATMENT

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

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

16 (1) the patient:

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

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

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

24 (2) the patient's physician:

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

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

6 Sec. 491.053. INFORMED CONSENT. (a) An eligible patient
7 may not receive an individualized investigational treatment unless
8 the patient provides written informed consent. If the patient is a
9 minor or lacks the mental capacity to provide informed consent, a
10 parent, legal guardian, managing conservator, or patient's agent as
11 defined by Section 166.151 may provide written informed consent on
12 the patient's behalf.

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

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

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

19 (2) an attestation that the patient concurs with the
20 patient's physician in believing that all currently approved and
21 conventionally recognized treatments are unlikely to prolong the
22 patient's life;

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

26 (4) a description, based on the physician's knowledge
27 of the proposed treatment in conjunction with an awareness of the

1 patient's disease or condition, of the potentially best and worst
2 outcomes of using the individualized investigational treatment,
3 and of the most likely outcome, including the possibility that new,
4 unanticipated, different, or worse symptoms might result and that
5 death could be hastened by the proposed treatment;

6 (5) a statement that the patient's health benefit plan
7 issuer or third-party administrator and provider are not obligated
8 to pay the cost of any care or treatments related to the use of the
9 individualized investigational treatment unless payment is
10 specifically required by law or contract;

11 (6) a statement that the patient's eligibility for
12 hospice care may be withdrawn if the patient begins curative
13 treatment with the individualized investigational treatment and
14 that care may be reinstated if this treatment ends and the patient
15 meets hospice eligibility requirements; and

16 (7) a statement that the patient understands the
17 patient is liable for all expenses related to the use of the
18 individualized investigational treatment and the liability extends
19 to the patient's estate, unless a contract between the patient and
20 the manufacturer of the individualized investigational treatment
21 states otherwise.

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

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

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

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

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

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

13 Sec. 491.055. DEBT LIABILITY ON DEATH OF PATIENT. If a
14 patient dies while being treated under an individualized
15 investigational treatment, the patient's heirs are not liable for
16 any outstanding debt related to the treatment or lack of health
17 coverage due to the treatment.

18 Sec. 491.056. NO PRIVATE CAUSE OF ACTION. This chapter does
19 not create a private cause of action against a manufacturer of an
20 individualized investigational treatment or against any other
21 person involved in the care of an eligible patient using the
22 individualized investigational treatment for any harm to the
23 eligible patient resulting from the individualized investigational
24 treatment if the manufacturer or other person is complying in good
25 faith with the terms of this chapter and has exercised reasonable
26 care.

27 Sec. 491.057. STATE MAY NOT INTERFERE WITH ACCESS TO

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

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

8 SUBCHAPTER C. HEALTH COVERAGE AND SERVICES

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

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

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

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

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

23 Sec. 491.104. COVERAGE OPTIONAL. A health benefit plan
24 issuer, third-party administrator, or governmental agency may, but
25 is not required to, provide coverage for the cost of an
26 individualized investigational treatment or the cost of services
27 related to the use of an individualized investigational treatment

1 under this chapter.

2 SUBCHAPTER D. HEALTH CARE PROVIDERS

3 Sec. 491.151. PROHIBITED ACTION AGAINST LICENSE OR

4 CERTIFICATION HOLDER. (a) A state licensing board may not revoke,
5 fail to renew, suspend, or take any action against a health care
6 provider's license issued under Title 3, Occupations Code, based
7 solely on the health care provider's recommendation to an eligible
8 patient regarding access to or treatment with an individualized
9 investigational treatment.

10 (b) The Health and Human Services Commission may not take
11 action against a health care provider's Medicare certification
12 based solely on the health care provider's recommendation that a
13 patient have access to an individualized investigational
14 treatment.

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