

By: King

H.B. No. 3318

A BILL TO BE ENTITLED

AN ACT

relating to access to individualized investigational treatments for patients with life-threatening or severely debilitating illnesses.

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

SECTION 1. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 491 to read as follows:

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 unique to and produced exclusively for use by a 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.

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

3 SUBCHAPTER B. ACCESS TO INDIVIDUALIZED INVESTIGATIONAL TREATMENT

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

11 Sec. 491.052. PATIENT ELIGIBILITY. A patient is eligible
12 to access an individualized investigational treatment under this
13 chapter if:

14 (1) the patient:

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

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

20 (C) has given written informed consent for access
21 to the treatment; and

22 (2) the patient's physician:

23 (A) attests to the patient's life-threatening
24 illness or severely debilitating illness and the patient's
25 eligibility under this section; and

26 (B) recommends the treatment for the patient
27 based on analysis of the patient's genomic sequence, human

1 chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene
2 products such as enzymes and other types of proteins, or
3 metabolites.

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

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

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

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

17 (2) the patient's attestation that the patient concurs
18 with the assessment of the patient's physician that all currently
19 approved and conventionally recognized treatments are unlikely to
20 prolong the patient's life;

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

24 (4) a description, based on the physician's knowledge
25 of the proposed treatment in conjunction with an awareness of the
26 patient's disease or condition, of the potentially best and worst
27 outcomes of using the treatment, and of the most likely outcome,

1 including the possibility that new, unanticipated, different, or
2 worse symptoms might result and that death could be hastened by the
3 treatment;

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

8 (6) a statement that the patient's eligibility for
9 hospice care may be withdrawn if the patient begins the treatment
10 and that care may be reinstated if the treatment ends and the
11 patient meets hospice eligibility requirements; and

12 (7) a statement that the patient understands the
13 patient is liable for all expenses related to the use of the
14 treatment and the liability extends to the patient's estate, unless
15 a contract between the patient and the manufacturer of the
16 treatment provides otherwise.

17 Sec. 491.054. ACCESS TO TREATMENT; COSTS. (a) A
18 manufacturer operating within an eligible health care facility and
19 in compliance with all applicable federal assurance laws and
20 regulations may make available an individualized investigational
21 treatment, and an eligible patient may request access to the
22 treatment from an eligible health care facility or manufacturer
23 operating within an eligible health care facility under this
24 chapter.

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

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

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

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

7 Sec. 491.055. DEBT LIABILITY ON DEATH OF PATIENT. If a
8 patient dies while receiving an individualized investigational
9 treatment, the patient's heirs are not liable for any outstanding
10 debt related to the treatment or lack of health coverage due to the
11 treatment.

12 Sec. 491.056. NO PRIVATE CAUSE OF ACTION. This chapter does
13 not create a private cause of action against a manufacturer of an
14 individualized investigational treatment or against any other
15 person involved in the care of an eligible patient using the
16 treatment for any harm to the patient resulting from the treatment
17 if the manufacturer or other person is complying in good faith with
18 the terms of this chapter and has exercised reasonable care.

19 Sec. 491.057. PROHIBITED STATE INTERFERENCE WITH ACCESS TO
20 TREATMENT. (a) An officer, employee, or agent of this state may
21 not block or attempt to block an eligible patient's access to an
22 individualized investigational treatment that complies with this
23 chapter and rules adopted under this chapter.

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

1 SUBCHAPTER C. HEALTH COVERAGE, COSTS, AND SERVICES

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

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

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

8 Sec. 491.102. COVERAGE OPTIONAL. A health benefit plan
9 issuer, third-party administrator, or governmental agency may, but
10 is not required to, provide coverage for the cost of an
11 individualized investigational treatment or the cost of services
12 related to the use of an individualized investigational treatment
13 under this chapter.

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

18 Sec. 491.104. GOVERNMENTAL AGENCY NOT RESPONSIBLE FOR
19 COSTS. This chapter does not require a governmental agency to pay
20 costs associated with the use, care, or treatment of a patient
21 accessing an individualized investigational treatment.

22 SUBCHAPTER D. HEALTH CARE PROVIDERS

23 Sec. 491.151. PROHIBITED ACTION AGAINST LICENSE HOLDER OR
24 MEDICAID PARTICIPANT. (a) A state licensing board may not revoke,
25 fail to renew, suspend, or take any action against a health care
26 provider's license issued under Title 3, Occupations Code, based
27 solely on the provider's recommendation to an eligible patient

1 regarding access to or treatment with an individualized
2 investigational treatment.

3 (b) The Health and Human Services Commission may not take
4 action against a health care provider that adversely affects the
5 provider's participation in Medicaid based solely on the provider's
6 recommendation for a patient to access an individualized
7 investigational treatment.

8 SECTION 2. This Act takes effect September 1, 2025.