BILL ANALYSIS

Senate Research Center

S.B. 984
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Health & Human Services
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Enrolled

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

In 2015, Texas enacted the Right to Try law to allow terminally ill patients access to investigational treatments that have completed an FDA-approved phase 1 clinical trial. Since then, the Right to Try has become a federal law. For patients with rare or ultra-rare diseases, however, where treatments are increasingly designed for an individual patient using his or her genetics, the existing pathway is not broad enough. This bill would extend the benefits of the original Right to Try law to these patients, empowering them to work with their physicians to seek cutting-edge, personalized treatments.

S.B. 984 seeks to expand the relevant statutes to even the playing field for patients who are not currently able to benefit from the protections of the original Texas Right to Try reform, giving them a fair chance to save their own lives. Oftentimes, with rare and ultra-rare diseases, there are no clinical trials because there are not enough patients or commercial viability to support them.

S.B. 984 establishes 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. It provides for multiple layers of patient protections such as informed consent and treatment risk disclosure and uses well-established protections such as the use of the federally-approved facilities' institutional review boards to ensure treatment protocols and patient safety.

S.B. 984 amends current law mends current law relating to access to individualized investigational treatments for patients with life-threatening or severely debilitating illnesses.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subtitle C, Title 6, Health and Safety Code, by adding Chapter 491, as follows:

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

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 491.001. DEFINITIONS. Defines "individualized investigational treatment," "life-threatening illness," and "severely debilitating illness."

SUBCHAPTER B. ACCESS TO INDIVIDUALIZED INVESTIGATIONAL TREATMENT

Sec. 491.051. HEALTH CARE FACILITY ELIGIBILITY. Provides that 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.

Sec. 491.052. PATIENT ELIGIBILITY. Provides that a patient is eligible to access an individualized investigational treatment under this chapter if the patient has a life-threatening illness or severely debilitating illness, has considered all other treatment options currently approved by the United States Food and Drug Administration, and has given written informed consent for access to the treatment and the patient's physician attests to the patient's life-threatening illness or severely debilitating illness and the patient's eligibility under this section and recommends the 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) Prohibits an eligible patient from accessing an individualized investigational treatment unless the patient provides written informed consent. Authorizes a parent, legal guardian, managing conservator, or patient's agent as defined by Section 166.151 (Definitions), if the patient is a minor or lacks the mental capacity to provide informed consent, to provide written informed consent on the patient's behalf.

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

(c) Requires that informed consent under this chapter include at a minimum certain information, attestations, and statements.

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

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

(c) Authorizes an eligible health care facility or manufacturer operating within an eligible health care facility to provide an individualized investigational treatment to an eligible patient without receiving compensation or require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the treatment.

Sec. 491.055. DEBT LIABILITY ON DEATH OF PATIENT. Provides that, if a patient dies while receiving 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. Provides that 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 treatment for any harm to the patient resulting from the 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. PROHIBITED STATE INTERFERENCE WITH ACCESS TO TREATMENT. (a) Prohibits an officer, employee, or agent of this state from blocking or attempting to block an eligible patient's access to an individualized investigational treatment that complies with this chapter and rules adopted under this chapter.

(b) Provides that, 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, COSTS, AND SERVICES

Sec. 491.101. HEALTH COVERAGE. Provides that this chapter does not affect the coverage required of an insurer under the Insurance Code or health care coverage of enrollees in clinical trials under Chapter 1379 (Coverage for Routine Patient Care Costs for Enrollees Participating in Certain Clinical Trials), Insurance Code.

Sec. 491.102. COVERAGE OPTIONAL. Provides that a health benefit plan issuer, third-party administrator, or governmental agency is authorized to, 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.

Sec. 491.103. HOSPITAL SERVICES. Provides that this chapter does not require a hospital or health care facility licensed under Subtitle B (Licensing of Health Facilities), Title 4 (Health Facilities), to provide new or additional services unless approved by the hospital or facility.

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

SUBCHAPTER D. HEALTH CARE PROVIDERS

Sec. 491.151. PROHIBITED ACTION AGAINST LICENSE HOLDER OR MEDICAID PARTICIPANT. (a) Prohibits a state licensing board from revoking, failing to renew, suspending, or taking any action against a health care provider's license issued under Title 3 (Health Professions), Occupations Code, based solely on the provider's recommendation to an eligible patient regarding access to or treatment with an individualized investigational treatment.

(b) Prohibits the Health and Human Services Commission from taking action against a health care provider that adversely affects the provider's participation in Medicaid based solely on the provider's recommendation for a patient to access an individualized investigational treatment.

SECTION 2. Effective date: September 1, 2025.