BILL ANALYSIS

S.B. 984
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Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

In 2015, Texas enacted H.B. 21, the Right to Try Act, to allow terminally ill patients access to investigational drugs, biological products, and devices that have completed a phase one clinical trial but have not yet been approved for general use by the FDA. Since then, a federal Right to Try Act has also been enacted. The bill sponsor has informed the committee, however, that the existing right to try pathways are not broad enough for patients with rare or ultra-rare diseases, for whom there often aren't clinical trials due to a lack of patients and commercial viability. S.B. 984 seeks to address this issue by providing for access to individualized investigational treatments for qualifying patients with life-threatening or severely debilitating illness.

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

S.B. 984 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. The bill establishes the following eligibility criteria for a patient to access an individualized investigational treatment:

- the patient has a life-threatening illness or severely debilitating illness, has considered all other treatment options currently approved by the FDA, and has given written informed consent for access to the treatment; and
- the patient's physician does the following:
    - attests to the patient's life-threatening illness or severely debilitating illness and the patient's eligibility; 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.

S.B. 984 prohibits an eligible patient from accessing 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 reference to certain provisions of the Advance Directives Act, may provide written informed consent on the patient's behalf. The bill requires informed consent for

access to an 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 treatments for the patient's disease or condition;
- the patient's attestation that the patient concurs with the assessment of the patient's physician 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 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 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 related to the use of the 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 the treatment and that care may be reinstated if the 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 treatment and the liability extends to the patient's estate unless a contract between the patient and the manufacturer of the treatment provides otherwise.

S.B. 984 does the following with respect to the provision of an individualized investigative treatment:

- 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 access to 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 manufacturer operating within an eligible health care facility to provide the 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.

If a patient dies while receiving the 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.

S.B. 984 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 patient resulting from the treatment if the manufacturer or other person is complying in good faith with the bill's terms and has exercised reasonable care.

S.B. 984 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. The bill establishes that counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this prohibition.

S.B. 984 establishes that its provisions do not affect the coverage required of an insurer under the Insurance Code or health care coverage for routine patient care costs for enrollees participating in certain clinical trials.

S.B. 984 authorizes a health benefit plan issuer, third-party administrator, or governmental agency to, but expressly does not require them 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. Additionally, the bill does not require the following:

- a licensed hospital or health care facility to provide new or additional services unless approved by the hospital or facility; and
- a governmental agency to pay costs associated with the use, care, or treatment of a patient accessing an individualized investigational treatment.

S.B. 984 prohibits a state licensing board from revoking, failing to renew, suspending, or taking any action against a health care provider's license issued under statutory provisions relating to health professions under the Occupations Code, based solely on the provider's recommendation to an eligible patient regarding access to or treatment with an individualized investigational treatment and 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.

S.B. 984 defines the following terms:

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

EFFECTIVE DATE

September 1, 2025.