SENATE BILL 282
By Watson

HOUSE BILL 192

By Terry

AN ACT to amend Tennessee Code Annotated, Title 53 and Title 63, relative to medical treatment.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, is amended by adding the following as a new part:

63-6-1301.

This part is known and may be cited as the "Individualized Investigational Treatment Act."

63-6-1302.

As used in this part:

(1) "Eligible facility" means an institution operating under principles of Federalwide Assurance (FWA) for the Protection of Human Subjects in accordance with 45 C.F.R. § 46 and 42 U.S.C. § 289(a);

(2) "Eligible patient" means an individual who meets all of the following criteria:

(A) Has a life-threatening or severely debilitating illness, attested to by a treating physician;

(B) Has, in consultation with a treating physician, considered all other treatment options currently approved by the United States food and drug administration;

(C) Has received a recommendation from the treating physician for use of an individualized investigational treatment for treatment of the life-threatening or severely debilitating illness;

(D) Has given written, informed consent for the use of the investigational drug, biological product, or device; and

(E) Has documentation from the patient's physician that the patient meets the requirements of this subdivision (2);

(3) "Individualized investigational treatment":

(A) Means drugs, biological products, or devices that are unique to and produced exclusively for use for an individual patient, based on the patient's own genetic profile; and

(B) Includes individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines;

(4) "Institution" has the same meaning as defined in 45 C.F.R. § 46.102(f);

(5) "Life-threatening or severely debilitating illness" has the same meaning as those terms are defined in 21 C.F.R. § 312.81; and

(6) "Written, informed consent" means a written document that is signed by the patient, the patient's parent, if the patient is a minor, the patient's legal guardian, or the patient's attorney-in-fact designated by the patient under title 34, chapter 6, part 2, and attested to by the patient's physician and a witness, and that, at a minimum, includes all of the following:

(A) An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers;

(B) 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;

(C) Clear identification of the specific proposed individualized investigational treatment that the patient is seeking to use;

(D) A description of the potentially best and worst outcomes of using the individualized investigational treatment and a realistic description of the most likely outcome. The description must include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description must be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(E) A release of liability relative to the treating physician, licensed healthcare providers, hospital, and manufacturer of the individualized investigational treatment;

(F) A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the individualized investigational treatment, unless they are specifically required to do so by law or contract;

(G) 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 such treatment ends and the patient meets hospice eligibility requirements; and

(H) A statement that the patient understands that the patient is liable for all expenses consequent to the use of the individualized investigational treatment and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the individualized investigational treatment states otherwise.

63-6-1303.

(a) A manufacturer operating within an eligible facility and pursuant to all applicable FWA laws and regulations may make available an individualized investigative treatment and an eligible patient may request an individualized investigational treatment from an eligible facility or manufacturer operating within an eligible facility under this part. This part does not require that a manufacturer make available an individualized investigational treatment to an eligible patient.

(b) An eligible facility or manufacturer operating within an eligible facility may do all of the following:

(1) Provide an individualized investigational treatment to an eligible patient without receiving compensation; and

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

63-6-1304.

(a) This part does not expand the coverage required of an insurer under title 56, chapter 7.

(b) A health plan, 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 part.

(c) This part does not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational treatment.

(d) This part does not require any hospital or facility licensed under title 68, chapter 11, or any physician or healthcare provider to provide any items or services unless a request by an eligible patient is approved by the hospital, facility, physician, or healthcare provider.

63-6-1305.

If a patient dies while being treated by an individualized investigational treatment, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

63-6-1306.

A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a healthcare provider's license issued under this title, based solely on the healthcare provider's recommendations to an eligible patient regarding access to or treatment with an individualized investigational treatment. An entity responsible for medicare certification shall not take action against a healthcare provider's medicare certification based solely on the healthcare provider's recommendation that a patient have access to an individualized investigational treatment.

63-6-1307.

An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an individualized investigational treatment. The rendering of counseling, advice, or a recommendation consistent with medical standards of care from a licensed healthcare provider is not a violation of this section.

63-6-1308.

(a) This part does not create a private cause of action against a manufacturer of an individualized investigational treatment or against any other person or entity involved in the care of an eligible patient using the individualized investigational treatment for any harm done to the eligible patient resulting from the individualized investigational treatment, if the manufacturer or other person or entity is complying in good faith with the terms of this part and has exercised reasonable care.

(b) This part does not affect any mandatory healthcare coverage for participation in clinical trials under § 56-7-2365.

SECTION 2. If any provision of this act or its application to any person or circumstance is held invalid, then the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end, the provisions of this act are severable.

SECTION 3. This act takes effect July 1, 2025, the public welfare requiring it.