Safeguard the Right to Try Cutting-Edge Medicine (Right to Try 2.0)

SEC. 1.

(1) As used in this act, and unless the context otherwise requires:

(a) "Life-threatening or severely debilitating illness," as defined in section 312.81 of Title 21, Code of Federal Regulations (or any successor regulation).

(b) "Eligible patient" means an individual who meets all of the following conditions:

(i) Has a life-threatening or severely debilitating illness, attested to by the patient's treating physician.

(ii) Has considered all other treatment options currently approved by the United States food and drug administration.

(iii) Has received a recommendation from his or her physician for an individualized investigational treatment, 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.

(iv) Has given written, informed consent for the use of the investigational drug, biological product, or device.

(v) Has documentation from his or her physician that he or she meets the requirements of this subdivision.

(c) "Individualized investigational treatment" means drugs, biological products, or devices that is unique to and produced exclusively for use for an individual patient, based on their own genetic profile. "Individualized investigational treatment" includes, but is not limited to, individualized gene therapy antisense oligonucleotides (ASO) and individualized neoantigen vaccines.

(d) "Written, informed consent" means a written document that is signed by the patient; parent, if the patient is a minor; legal guardian; or patient advocate designated by the patient under section of the estates and protected individual code, and attested to by the patient's physician and a witness and that, at a minimum, includes all of the following:

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

(ii) An attestation that the patient concurs with his or her Physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.

(iii) Clear identification of the specific proposed individualized investigational drug, biological product, or device that the patient is seeking to use.

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

(v) 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 drug, biological product, or device, unless they are specifically required to do so by law or contract.

(vi) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the individualized investigational drug, biological product, or device and that care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

(vii) A statement that the patient understands that he or she is liable for all expenses consequent to the use of the individualized investigational drug, biological product, or device and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

(e.) "Eligible facility" means an institution that is operating under a Federalwide Assurance (FWA) for the Protection of Human Subjects under 42 U.S.C. 289(a) and 45 CFR Part 46. And eligible facility is subject to the FWA laws, regulations, policies, and guidelines including renewals or updates.

SEC. 2.

(1) 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 drug, biological product, or device from an eligible facility or manufacturer operating within an eligible facility under this act. This act does not require that a manufacturer make available an individualized investigational drug, biological product, or device to an eligible patient.

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

(a) Provide an individualized investigational drug, biological product, or device to an eligible patient without receiving compensation.

(b) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

SEC. 3.

(1) This act does not expand the coverage required of an insurer under the insurance code of

(2) A health plan, third party administrator, or governmental agency may, but is not required to, provide coverage for the cost of an individualized investigational drug, biological product, or device, or the cost of services related to the use of an individualized investigational drug, biological product, or device under this act.

(3) This act does not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational drug, biological product, or device.

(4) This act does not require a hospital or facility licensed under part of the public health code, to provide new or additional services, unless approved by the hospital or facility.

SEC. 4.

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

SEC. 5.

A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a health care provider's license issued under article of the public health code, and based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an individualized investigational drug, biological product, or device. An entity responsible for Medicare certification shall not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an individualized investigational drug, biological product, or device.

SEC. 6.

An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an individualized investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

SEC. 7.

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

(2) This act does not affect any mandatory health care coverage for participation in clinical trials under the insurance code of _____.