By Senator Rodriguez

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A bill to be entitled

An act relating to individualized investigational treatments for life-threatening or severely debilitating illnesses; creating s. 499.0296, F.S.; defining terms; authorizing eligible patients to request and receive individualized investigational treatment if they meet specified conditions; authorizing eligible facilities and certain manufacturers to provide individualized investigational treatments to eligible patients; providing construction with respect to insurance coverage and health care services related to an eligible patient's use of an individualized investigational treatment; providing that an eligible patient's heirs are not liable for any outstanding debt related to the patient's use of an individualized investigational treatment; prohibiting a licensing board and certain state entities from taking disciplinary action against a physician solely for recommending an individualized investigational treatment for an eligible patient; prohibiting officials, employees, and agents of the state from blocking or attempting to block an eligible patient's access to individualized investigational treatment; providing construction; providing that a cause of action may not arise against the manufacturer of an individualized investigational treatment or any person or entity involved in the care of an eligible patient using such treatment under certain circumstances;

providing construction; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.0296, Florida Statutes, is created to read:

499.0296 Patient right to try individualized investigational treatment.—

(1) As used in this section, the term:

(a) "Eligible facility" means an institution that is operating under a Federalwide Assurance (FWA) for the Protection of Human Subjects under 42 U.S.C. s. 289(a) and 45 C.F.R. part 46 subject to the FWA laws, regulations, policies, and guidelines.

(b) "Eligible patient" means an individual authorized to receive individualized investigational treatment under this section.

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

(d) "Life-threatening or severely debilitating illness" has the same meaning as provided in 21 C.F.R. s. 312.81.

(e) "Written, informed consent" means a written document that is signed by a patient, a parent or legal guardian of a patient who is a minor, a court-appointed guardian for a patient, or a health care surrogate designated by a patient,

attested to by the patient's physician and a witness, and includes all of the following:

1. An explanation of the currently approved products and treatments for the life-threatening or severely debilitating illness from which the patient suffers.

2. 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.

3. Clear identification of the specific proposed individualized investigational treatment that the patient is seeking to use.

4. A description of all of the best and worst potential 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 may result and that death could be hastened by the proposed treatment. The description must be based on the physician's knowledge of the proposed individualized investigational treatment in conjunction with an awareness of the patient's life-threatening or severely debilitating illness.

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

6. 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 hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements.

7. A statement that the patient understands that he or she 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.

(2) In addition to the options available under s. 499.0295, an eligible patient may request and receive individualized experimental treatment if he or she meets all of the following conditions:

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

(b) Has considered all other treatment options currently approved by the United States Food and Drug Administration.

(c) 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.

(d) Has given written, informed consent for the use of the individualized investigational treatment.

(e) Has documentation from his or her physician demonstrating that he or she meets the requirements of this section.

(3) Upon the request of an eligible patient, an eligible

facility or a manufacturer operating within an eligible facility and pursuant to all applicable FWA laws and regulations may, but is not required to, do all of the following:

(a) Make available an individualized investigational treatment requested by an eligible patient.

(b) Provide an individualized investigational treatment to an eligible patient without receiving compensation.

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

(4) A health plan, third-party administrator, or governmental agency may, but is not required to, provide coverage for the cost of, or the cost of services related to the use of, an individualized investigational treatment under this section.

(5) This section does not require a hospital or health care facility licensed under chapter 395 to provide new or additional services unless those services are approved by the hospital or health care facility.

(6) If an eligible patient dies while being treated by an individualized investigational treatment under this section, the patient's heirs are not liable for any outstanding debt related to the patient's use of the treatment.

(7) A licensing board may not revoke, fail to renew, suspend, or take any action against a physician's license issued under chapter 458 or chapter 459 based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an individualized investigational treatment under this section. A state entity responsible for Medicare

certification may not take action against a physician's Medicare certification based solely on the physician's recommendation that an eligible patient use an individualized investigational treatment.

(8) An official, an employee, or any agent of the state may not block or attempt to block an eligible patient's access to an individualized investigational treatment. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

(9) This section 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 use of the individualized investigational treatment if the manufacturer or other person or entity complied in good faith with the terms of this section and exercised reasonable care.

(10) This section does not expand the coverage an insurer must provide under the Florida Insurance Code.

Section 2. This act shall take effect July 1, 2025.