A bill to be entitled

An act relating to individualized investigational treatments; creating s. 381.992, F.S.; providing definitions; authorizing certain actions by eligible facilities, manufacturers operating within eligible facilities, and eligible patients relating to individualized investigational treatments; authorizing health plans, third-party administrators, and governmental agencies to provide coverage for the cost of an individualized investigational drug, biological product, or device, or the cost of certain services; limiting liability; prohibiting licensing boards, disciplinary subcommittees, and entities responsible for Medicare certification from taking certain actions against a health care provider's license under certain circumstances; prohibiting certain persons from blocking or attempting to block an eligible patient's access to an individualized investigational drug, biological product, or device; providing construction; providing an effective date.

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

Section 1. Section 381.992, Florida Statutes, is created to read:

381.992 Individualized investigational treatments.—

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

(a) "Eligible facility" means an institution that is operating under a Federalwide Assurance (FWA), and is subject to the FWA laws, regulations, policies, and guidelines including renewals or updates, for the protection of human subjects in research under 42 U.S.C. s. 289(a) and 45 C.F.R. part 46.

(b) "Eligible patient" means an individual who has:

1. A life-threatening or severely debilitating illness as determined by the patient's treating physician.

2. Considered all other treatment options currently approved by the federal Food and Drug Administration.

3. Received a recommendation from his or her treating physician for an individualized investigational treatment based on analysis of the patient's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products, or metabolites.

4. Given written, informed consent for the use of the individualized investigational drug, biological product, or device.

5. Documentation from his or her treating physician that he or she meets the requirements of this section.

(c) "Individualized investigational treatment" means individualized investigational drugs, biological products, or devices that are unique to and produced exclusively for use by

an individual patient based on his or her 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 in 21 C.F.R. s. 312.81 or any successor regulation.

(e) "Written, informed consent" means a written document that is signed by the patient; a parent, if the patient is a minor; a legal guardian; or a patient advocate designated by the patient and attested to by the patient's physician and a witness. The written, informed consent shall include, but is not limited to, all of the following:

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

2. A determination that the patient agrees with his or her treating physician that all currently approved products and treatments are unlikely to prolong the patient's life.

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

4. 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 from, and death could be hastened by, the proposed treatment. The description shall be based on the treating physician's knowledge of the proposed treatment and knowledge of the patient's condition.

5. A statement that the patient's health insurance plan or third-party administrator and health care provider are not obligated to pay for any care or treatments resulting from the use of the individualized investigational drug, biological product, or device, unless specifically required to do so by general 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 such treatment ends and the patient meets the eligibility requirements for hospice care.

7. A statement that the patient understands that he or she is liable for all expenses for 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 such drug, product, or device states otherwise.

(2)(a) Pursuant to all applicable FWA laws and

regulations, an eligible facility or a manufacturer operating within an eligible facility may provide an individualized investigational treatment and an eligible patient may request an individualized investigational drug, biological product, or device from an eligible facility or a manufacturer operating within an eligible facility. This section does not require that a manufacturer operating within an eligible facility provide an individualized investigational drug, biological product, or device to an eligible patient.

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

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

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

(3)(a) A health plan, third-party administrator, or governmental agency may 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.

(b) This subsection does not:

1. Expand the coverage required of an insurer under the

Florida Insurance Code.

2. Require a governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational drug, biological product, or device.

3. Require a hospital or facility licensed under chapter 395 to provide new or additional services, unless approved by the hospital or facility.

(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.

(5) A licensing board or disciplinary subcommittee may not revoke, fail to renew, suspend, or take any action against a health care provider's license based solely on the health care provider's recommendation to an eligible patient regarding access to or treatment with an individualized investigational drug, biological product, or device. An entity responsible for Medicare certification may not take any action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to or be treated with an individualized investigational drug, biological product, or device.

(6) An official, employee, or agent of this state may 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 health care provider is not a violation of this section.

(7) This section does not:

(a) 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 section and has exercised reasonable care.

(b) Affect any mandatory health care coverage for participation in clinical trials under the Florida Insurance Code.

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