ENROLLED

2024 Regular Session

ACT No. 750

HOUSE BILL NO. 899

BY REPRESENTATIVES WRIGHT, BERAULT, CREWS, EGAN, GALLE, AND MYERS

AN ACT

To enact Part VIII of Chapter 5-G of Title 40 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 40:1300.71 through 1300.79, relative to individualized investigational treatments, drugs, or devices; to enact the Hope for Louisiana Patients Law; to provide access to individualized investigative treatment for patients with life-threatening illnesses; to provide a short title; to provide definitions; to permit the expansion of existing insurance coverage provisions; to prohibit actions against healthcare providers; to establish provisions for the death of a patient; to prohibit private causes of action and insurance mandates; to provide for severability; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. Part VIII of Chapter 5-G of Title 40 of the Louisiana Revised Statutes of 1950, comprised of R.S. 40:1300.71 through 1300.79, is hereby enacted to read as follows:

PART VIII. HOPE FOR LOUISIANA PATIENTS

§1300.71. Short title

This Part shall be known and may be cited as the "Hope for Louisiana Patients Law".

§1300.72. Definitions

As used in this Part, the following terms have the meanings ascribed to them:

(1) "Eligible facility" means an institution that is operating with a Federalwide Assurance for the Protection of Human Subjects, in accordance with 42 U.S.C. 289(a) and 45 CFR Part 46, and an eligible facility that is subject to the

Federalwide Assurance for the Protection of Human Subjects laws, regulations, policies, and guidelines, including renewals and updates.

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

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

(b) Has received a recommendation from his 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.

(c) Has a life-threatening, severely debilitating illness or serious disease or condition associated with morbidity that has a substantial impact on day-to-day functioning and is attested to by the patient's treating physician.

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

(e) Has documentation from his physician that he meets the requirements of this Part.

(3) "Individualized investigational treatment" means drugs, biological products, or devices that are unique to and produced exclusively for use for an individual patient, based on his own genetic profile.

(a) "Individualized investigational treatment" includes but is not limited to individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.

(b) "Individualized investigational treatment" does not include any drug, biological product, or device derived from human primary or secondary embryonic stem cells or cell lines, or tissues or cells derived from abortion, but does include any drug, biological product, or device derived from human perinatal tissues, cells, and secreted factors not obtained from an abortion.

(4) "Life-threatening or severely debilitating illness," has the same meaning as provided in 21 CFR 312.81, or any successor law or regulation, as applicable.

(5) "Written, informed consent" means a written document that is signed by the patient, or if the patient is a minor, by any person authorized to consent in accordance with the Louisiana Medical Consent Law, R.S. 40:1159.1, et seq., 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 illness, disease, or condition from which the patient suffers.

(b) An attestation that the patient concurs with his 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 drug, biological product, or device that the patient is seeking to use.

(d)(i) 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.

(ii) 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.

(iii) The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(e) 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.

(f) 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.

(g) A statement that the patient understands that he 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.

§1300.73. Individualized investigational drugs; facility and manufacturer abilities

A. A manufacturer operating within an eligible facility and in accordance with all applicable Federalwide Assurance for the Protection of Human Subjects 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 in accordance with this Part. This Part shall not require a manufacturer to make available an individualized investigational drug, biological product, or device 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 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 investigational drug, biological product, or device.

§1300.74. Coverage expansion; permissible; not required

A. This Part shall not expand the coverage required of an insurer in accordance with any provisions of Title 22 of the Louisiana Revised Statutes of 1950.

B. 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 in accordance with this Part.

C. This Part shall 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.

D. This Part shall not require a hospital or facility licensed in accordance with R.S. 40:2006(A) and operating or planning to operate within the state to provide new or additional services unless approved by the hospital or facility.

§1300.75. Patient death; insurance provisions

If a patient's death is proximately caused by treatment with an individualized investigational drug, biological product, or device, the patient's estate, heirs, or devisees are not liable for any debt remaining after payment by insurance for charges directly incurred for the treatment. However, this provision shall not provide an exemption to liability for charges for non-experimental treatments provided to the patient, including non-experimental treatments rendered to the patient due to complications or consequences of the experimental treatment.

§1300.76. Prohibition of actions taken against licensure of healthcare providers

A. A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a healthcare provider's license issued in accordance with Chapter 15 of Title 37 of the Louisiana Revised Statutes of 1950 based solely on the healthcare provider's recommendations to an eligible patient regarding access to or treatment with an individualized investigational drug, biological product, or device.

B. 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 has access to an individualized investigational drug, biological product, or device.

§1300.77. Eligible patient's access to individualized investigational drugs, biological products, or devices

A. 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.

B. Providing counseling, advice, or a recommendation consistent with medical standards of care from a licensed healthcare provider shall not be a violation of this Section.

§1300.78. Prohibition of private causes of action and insurance mandates

A. This Part shall 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 Part and has exercised reasonable care.

B. This Part shall not affect any mandatory healthcare coverage for participation in clinical trials in accordance with any provisions provided in Title 22 of the Louisiana Revised Statutes of 1950.

§1300.79. Severability

If one or more provisions of this Part or the application thereof is found to be unconstitutional, the provision shall be declared severable and the balance of this Part shall remain effective notwithstanding such unconstitutionality.

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____