

2024 Regular Session

HOUSE BILL NO. 899

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

1 AN ACT

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

11 Be it enacted by the Legislature of Louisiana:

12 Section 1. Part VIII of Chapter 5-G of Title 40 of the Louisiana Revised Statutes of  
13 1950, comprised of R.S. 40:1300.71 through 1300.79, is hereby enacted to read as follows:

14 PART VIII. HOPE FOR LOUISIANA PATIENTS

15 §1300.71. Short title

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

18 §1300.72. Definitions

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

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

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

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

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

7 (b) Has received a recommendation from his physician for an individualized  
8 investigational treatment, based on analysis of the patient's genomic sequence,  
9 human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products  
10 such as enzymes and other types of proteins, or metabolites.

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

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

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

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

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

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

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

1           (5) "Written, informed consent" means a written document that is signed by  
2           the patient, or if the patient is a minor, by any person authorized to consent in  
3           accordance with the Louisiana Medical Consent Law, R.S. 40:1159.1, et seq., and  
4           attested to by the patient's physician and a witness and that, at a minimum, includes  
5           all of the following:

6           (a) An explanation of the currently approved products and treatments for the  
7           illness, disease, or condition from which the patient suffers.

8           (b) An attestation that the patient concurs with his physician in believing that  
9           all currently approved and conventionally recognized treatments are unlikely to  
10          prolong the patient's life.

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

13          (d)(i) A description of the potentially best and worst outcomes of using the  
14          individualized investigational drug, biological product, or device and a realistic  
15          description of the most likely outcome.

16          (ii) The description shall include the possibility that new, unanticipated,  
17          different, or worse symptoms might result and that death could be hastened by the  
18          proposed treatment.

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

21          (e) A statement that the patient's health plan or third-party administrator and  
22          provider are not obligated to pay for any care or treatments consequent to the use of  
23          the individualized investigational drug, biological product, or device, unless they are  
24          specifically required to do so by law or contract.

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

29          (g) A statement that the patient understands that he is liable for all expenses  
30          consequent to the use of the individualized investigational drug, biological product,

1 or device and that this liability extends to the patient's estate, unless a contract  
2 between the patient and the manufacturer of the drug, biological product, or device  
3 states otherwise.

4 §1300.73. Individualized investigational drugs; facility and manufacturer abilities

5 A. A manufacturer operating within an eligible facility and in accordance  
6 with all applicable Federalwide Assurance for the Protection of Human Subjects  
7 laws and regulations may make available an individualized investigative treatment  
8 and an eligible patient may request an individualized investigational drug, biological  
9 product, or device from an eligible facility or manufacturer operating within an  
10 eligible facility in accordance with this Part. This Part shall not require a  
11 manufacturer to make available an individualized investigational drug, biological  
12 product, or device to an eligible patient.

13 B. An eligible facility or manufacturer operating within an eligible facility  
14 may do all of the following:

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

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

19 §1300.74. Coverage expansion; permissible; not required

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

23 B. A health plan, third-party administrator, or governmental agency may  
24 provide coverage for the cost of an individualized investigational drug, biological  
25 product, or device or the cost of services related to the use of an individualized  
26 investigational drug, biological product, or device in accordance with this Part.

27 C. This Part shall not require any governmental agency to pay costs  
28 associated with the use, care, or treatment of a patient with an individualized  
29 investigational drug, biological product, or device.

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

4           §1300.75. Patient death; insurance provisions

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

12          §1300.76. Prohibition of actions taken against licensure of healthcare providers

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

19           B. An entity responsible for Medicare certification shall not take action  
20           against a healthcare provider's Medicare certification based solely on the healthcare  
21           provider's recommendation that a patient has access to an individualized  
22           investigational drug, biological product, or device.

23          §1300.77. Eligible patient's access to individualized investigational drugs,  
24          biological products, or devices

25           A. An official, employee, or agent of this state shall not block or attempt to  
26           block an eligible patient's access to an individualized investigational drug, biological  
27           product, or device.

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

1           §1300.78. Prohibition of private causes of action and insurance mandates

2                   A. This Part shall not create a private cause of action against a manufacturer  
3                   of an individualized investigational drug, biological product, or device or against any  
4                   other person or entity involved in the care of an eligible patient using the  
5                   individualized investigational drug, biological product, or device for any harm done  
6                   to the eligible patient resulting from the individualized investigational drug,  
7                   biological product, or device, if the manufacturer or other person or entity is  
8                   complying in good faith with the terms of this Part and has exercised reasonable  
9                   care.

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

13           §1300.79. Severability

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

\_\_\_\_\_  
SPEAKER OF THE HOUSE OF REPRESENTATIVES

\_\_\_\_\_  
PRESIDENT OF THE SENATE

\_\_\_\_\_  
GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: \_\_\_\_\_