Regular Session, 2014

HOUSE BILL NO. 891

BY REPRESENTATIVES STOKES AND SIMON

HEALTH/MEDICAL TREATMENT: Authorizes access to investigational treatments for terminally ill patients

AN ACT

To enact Part LXXV of Chapter 5 of Title 40 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 40:1300.381 through 1300.385, relative to access to treatment for terminally ill patients; to provide for findings, definitions, intent, and construction; to authorize provision of certain pharmaceutical and therapeutic products by manufacturers; to specify that gratuitous provision and insurance coverage of certain treatments are not required; to provide for limitation of liability; to prohibit actions against licenses of physicians in specific instances; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. Part LXXV of Chapter 5 of Title 40 of the Louisiana Revised Statutes of 1950, comprised of R.S. 40:1300.381 through 1300.385, is hereby enacted to read as follows:

PART LXXV. ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS

§1300.381. Short title

This Part shall be known and may be cited as the "Right To Try Act".

§1300.382. Legislative findings

The Legislature of Louisiana hereby finds and declares the following:

(1) The process of approval for investigational drugs, biological products, and devices in the United States often takes many years.

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(2) A patient who has a terminal illness does not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States Food and Drug Administration.

(3) The standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to terminally ill patients.

(4) A patient with a terminal illness has a fundamental right to attempt to preserve his own life by accessing available investigational drugs, biological products, and devices.

(5) Whether to use available investigational drugs, biological products, or devices is a decision that rightfully should be made by the patient with a terminal illness in consultation with his physician, and is not a decision to be made by the government.

§1300.383. Definitions

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

(1) "Eligible patient" means a person to whom all of the following criteria apply:

(a) Has a terminal illness.

(b) As determined by the person's physician, has no comparable or satisfactory treatment options that are approved by the United States Food and Drug Administration and available to diagnose, monitor, or treat the person's disease or condition, and the probable risk to the person from the investigational drug, biological product, or device is not greater than the probable risk from the person's disease or condition.

(c) Has received a prescription or recommendation from his physician for an investigational drug, biological product, or device.

(d) Has given his consent in writing for the use of the investigational drug, biological product, or device; or, if he is a minor or lacks the mental capacity to

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provide consent, a parent or legal guardian has given consent in writing on his behalf.

(e) Has documentation from his physician indicating that he has met the requirements provided in this Part.

(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a United States Food and Drug Administration approved clinical trial, but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial.

(3) "Terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely. This diagnosis shall be confirmed by a second independent evaluation by a board-certified physician in an appropriate speciality.

§1300.384. Availability of drugs, biological products, and devices; costs; insurance coverage

A.(1) A manufacturer of an investigational drug, biological product, or device may make available such drug, product, or device to eligible patients in accordance with the provisions of this Section.

(2) Nothing in this Section shall be construed to require a manufacturer to make available any drug, product, or device.

B. A manufacturer may do any of the following:

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

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

C.(1) A health insurance issuer may choose to provide coverage for the cost of an investigational drug, biological product, or device.

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(2) Nothing in this Section shall be construed to require a health insurance issuer to provide coverage for the cost of any investigational drug, biological product, or device.

§1300.385. Limitation of liability

Notwithstanding any provision of law to the contrary, a physician who prescribes an investigational drug, biological product, or device to an eligible patient pursuant to the provisions of this Part shall be immune from civil liability, including but not limited to any cause of action arising under R.S. 40:1299.41 et. seq., for any adverse action, condition, or other outcome resulting from the patient's use of the investigational drug, biological product, or device.

Section 2. The Louisiana State Law Institute is hereby directed to redesignate the numbers of the Sections of statute enacted by this Act in a manner that comports with the technical recodification provisions of the Act which originated as House Bill No. 667 of this 2014 Regular Session of the Legislature.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

Stokes HB No. 891

Abstract: Authorizes access to investigational drugs, biological products, and devices for terminally ill patients.

Proposed law establishes findings concerning barriers that terminally ill patients may face in access to potentially life-preserving treatments.

Proposed law provides the following definitions for purposes of proposed law:

(1) "Eligible patient" means a person who meets all of the following criteria:

(a) Has a terminal illness.

(b) As determined by the person's physician, has no comparable or satisfactory treatment options that are approved by the U.S. Food and Drug Administration and available to diagnose, monitor, or treat the person's disease or condition, and the probable risk to the person from the investigational drug, biological product, or device is not greater than the probable risk from the person's disease or condition.

(c) Has received a prescription or recommendation from his physician for an investigational drug, biological product, or device.

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(d) Has given his consent in writing for the use of the investigational drug, biological product, or device; or, if he is a minor or lacks the mental capacity to provide consent, a parent or legal guardian has given consent in writing on his behalf.

(e) Has documentation from his physician indicating that he has met the requirements provided in proposed law.

(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a U.S. Food and Drug Administration approved clinical trial, but has not been approved for general use by the U.S. Food and Drug Administration and remains under investigation in a clinical trial.

(3) "Terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely. Provides that this diagnosis shall be confirmed by a second independent evaluation by a board-certified physician in an appropriate speciality.

Proposed law authorizes manufacturers of investigational drugs, biological products, and devices to make available those drugs, products, and devices to eligible patients. Provides, however, that nothing in proposed law shall be construed to require provision of any drug, product, or device by a manufacturer.

Proposed law authorizes a manufacturer to provide an investigational drug, biological product, or device to an eligible patient with or without compensation.

Proposed law authorizes health insurers to provide coverage for the cost of an investigational drug, biological product, or device. Specifies that nothing in proposed law shall be construed to require such coverage by health insurers.

Proposed law provides that a physician who prescribes an investigational drug, biological product, or device pursuant to proposed law shall be immune from civil liability, including but not limited to any cause of action arising under medical malpractice provisions of present law, for any adverse outcome resulting from a patient's use of the investigational drug, biological product, or device pursuant to proposed law.

Proposed law provides that proposed law shall be known and may be cited as the Right To Try Act.

(Adds R.S. 40:1300.381-1300.385)

Summary of Amendments Adopted by House

Committee Amendments Proposed by House Committee on Health and Welfare to the original bill.

1. In the set of criteria for a person to be considered an "eligible patient" pursuant to proposed law, deleted consideration by the person of all other treatment options approved by the U.S. Food and Drug Administration (FDA); and added in lieu thereof determination by a physician that the person has no comparable or satisfactory FDA-approved treatment options available, and the probable risk from the investigational treatment is not greater than the probable risk from the disease or condition.

2. Relative to consent for types of treatment provided for in proposed law, deleted requirement that the consent the patient gives in writing be informed consent.

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3. Revised definition of "terminal illness" in proposed law to provide that such illness be one that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely. Provided that this diagnosis shall be confirmed by a second independent evaluation by a board-certified physician in an appropriate speciality.

4. Deleted provision prohibiting the La. State Board of Medical Examiners from revoking, failing to renew, or taking any other action against the license of a physician based solely upon the physician's recommendation regarding or prescription for or treatment with an investigational drug, biological product, or device.

5. Added provision establishing that a physician who prescribes an investigational drug, biological product, or device pursuant to proposed law shall be immune from civil liability, including but not limited to any cause of action arising under medical malpractice provisions of present law, for any adverse outcome resulting from a patient's use of the investigational drug, biological product, or device.

6. Deleted provision establishing a fine of $1,500 or less to be imposed upon any official, employee, or agent of the state who blocks or attempts to block a patient's access to an investigational drug, biological product, or device provided for in proposed law.

7. Made technical changes.

House Floor Amendments to the engrossed bill.

1. Relative to consent that a parent or legal guardian gives on behalf of a minor or a person lacking mental capacity to give consent for treatment provided for in proposed law, deleted requirement that the consent the parent or guardian gives in writing be informed consent.

2. In provisions relative to the clinical trial that a drug, product, or device must complete pursuant to proposed law, added provision stipulating that such trial is a United States Food and Drug Administration approved clinical trial.

3. Deleted legislative declaration indicating that allowing for the provisions of proposed law to apply to patients with nonterminal illnesses furthers the purpose of proposed law.

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