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 1300.386, 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 prohibit actions against licenses of physicians in specific instances; to provide for a penalty; 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 1300.386, 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.

(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 who meets all of the following criteria:

(a) Has a terminal illness.

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

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

(d) Has given his informed 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 informed consent, a parent or legal guardian has given informed 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 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 measures, can reasonably be expected to result in death in twenty-four months or less.

§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.

(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. Action against physician license prohibited

Notwithstanding any provision of law to the contrary, the Louisiana State Board of Medical Examiners shall not revoke, fail to renew, or take any other action against the license of a physician issued pursuant to the provisions of R.S. 37:1261 et seq. based solely upon the recommendation of the physician to an eligible patient

regarding or prescription for or treatment with an investigational drug, biological product, or device.

§1300.386. Penalty

Any official, employee, or agent of this state who blocks or attempts to block access by an eligible patient to an investigational drug, biological product, or device shall be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not more than one thousand five hundred dollars.

Section 2. The legislature hereby declares that allowing for the provisions of the Right To Try Act to apply to patients with nonterminal illnesses furthers the purpose of this Act.

Section 3. 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. ____ 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) Has considered all other treatment options approved by the United States Food and Drug Administration.

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

(d) Has given his informed 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 informed consent, a parent or legal guardian has given informed 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 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 measures, can reasonably be expected to result in death in 24 months or less.

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 prohibits 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 his recommendation to an eligible patient regarding or prescription for or treatment with an investigational drug, biological product, or device.

Proposed law provides that any official, employee, or agent of the state who blocks or attempts to block access by an eligible patient to an investigational drug, biological product, or device shall be guilty of a misdemeanor punishable by a fine of not more than $1,500.

Proposed law provides that proposed law shall be known and may be cited as the Right To Try Act. Declares that allowing for the provisions of the Right To Try Act to apply to patients with nonterminal illnesses furthers the purpose of proposed law.

(Adds R.S. 40:1300.381-1300.386)