ENROLLED

Regular Session, 2014

ACT No. 346

HOUSE BILL NO. 891

BY REPRESENTATIVES STOKES AND SIMON

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 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 1300.386, 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 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 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.

(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.

§1300.386. 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 when such recommendation, prescription, or treatment is undertaken in strict conformance with the provisions of this Part.

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.

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____