DIGEST

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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)