RÉSUMÉ DIGEST

ACT 750 (HB 899) **2024 Regular Session** **Wright**

Relative to investigational treatments, drugs, and devices, new law shall be known and may be cited as the "Hope for Louisiana Patients Law".

New law defines "eligible facility", "eligible patient", "individualized investigational treatment", "life-threatening or severely debilitating illness", and "written, informed consent".

New law allows a manufacturer operating within an eligible facility that complies with federal laws and regulations to make available an individualized investigative treatment to an eligible patient.

New law also allows an eligible patient to request an individualized investigational drug, biological product, or device from an eligible facility or manufacturer operating within an eligible facility in accordance with new law.

New law further provides that a manufacturer shall not be required to make available an individualized investigational drug, biological product, or device to an eligible patient.

New law allows an eligible facility or manufacturer operating within an eligible facility to do all of the following:

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

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

New law does not require expansion of the coverage required for an insurer in accordance with any provisions set forth in existing law.

New law allows a health plan, third-party administrator, or governmental agency to provide coverage for the cost of an individualized investigational drug, biological product, or device, or the cost of services related to the use of an individualized investigational drug, biological product, or device.

New law does not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational drug, biological product, or device. New law also does not require a hospital or facility licensed in accordance with existing law to provide new or additional services, unless approved by the hospital or facility.

New law establishes certain provisions in the event of a patient's death as a result of treatment with an individualized investigational drug, biological product, or device.

New law provides that a licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a healthcare provider's license issued in accordance with existing law based solely on the healthcare provider's recommendations to an eligible patient regarding access to or treatment with an individualized investigational drug, biological product, or device.

New law provides that an entity responsible for Medicare certification shall not take action against a healthcare provider's Medicare certification based solely on the healthcare provider's recommendation.

New law prohibits an official, employee, or agent of this state from blocking or attempting to block an eligible patient's access to an individualized investigational drug, biological product, or device.

New law provides that the provision of counseling, advice, or a recommendation consistent with medical standards of care from a licensed healthcare provider is also permitted in accordance with new law.

New law provides that nothing in new law shall create a private cause of action against a manufacturer of an individualized investigational drug, biological product, or device or against any other person or entity involved in the provision of such care. New law shall not affect any mandatory healthcare coverage for participation in clinical trials in accordance with existing law.

New law declares that if any provisions of new law or the application thereof to any person or circumstance is found to be unconstitutional, the new law provision shall be severable and the other provisions of new law shall remain effective notwithstanding such unconstitutionality.

Effective August 1, 2024.

(Adds R.S. 40:1300.71-1300.79)