CS/CS/HB 269 — Experimental Treatments for Terminal Conditions

by Insurance and Banking Subcommittee; Health Innovation Subcommittee; and Rep. Pilon and others (CS/CS/SB 1052 by Fiscal Policy Committee; Health Policy Committee; and Senators Brandes and Sobel)

The bill creates the "Florida Right to Try Act" (Act), which provides a framework in which an eligible patient with a terminal condition may access investigational drugs, biological products, and devices from the manufacturer after phase one clinical trials. A terminal condition is specifically defined under the Act as a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.

The Act also defines and requires written informed consent by the patient, the parent of a minor patient, a patient's court-appointed guardian or the patient's health care surrogate. The written, informed consent document must include:

- An explanation of the currently approved products and treatments for the patient's terminal condition;
- An attestation that the patient concurs with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life;
- Identification of the specific investigational drug, biological product, or device (investigational product) that the patient is seeking to use;
- A realistic description of the most likely outcome of using the investigational product;
- A statement that the patient's health plan or third party administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational product unless required to do so by law or contract;
- A statement that the patient's eligibility for hospice may be withdrawn if the patient begins treatment with the investigational product and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements; and
- A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational product and that liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational product states otherwise.

The bill prohibits actions against a physician's license based solely on his or her recommendation regarding access to or treatment with an investigational product under this Act.

The bill does not create a private cause of action against the manufacturer of an investigational product against a person or entity involved in the care of an eligible patient who is using the investigational product if the manufacturer or other person or entity complies in good faith with this Act and exercises reasonable care.

If approved by the Governor, these provisions take effect July 1, 2015.
Vote: Senate 39-1; House 113-0