Session of 2015

HOUSE BILL No. 2004

By Representatives Hildabrand, Kiegerl and McPherson

12-19

AN ACT creating the Kansas right to try act.

Be it enacted by the Legislature of the State of Kansas:

Section 1. The provisions of sections 1 through 7, and amendments thereto, shall be known and may be cited as the Kansas right to try act.

Sec. 2. (a) The legislature hereby finds and declares that:

(1) The process of approval for investigational drugs, biological products, and devices in the United States protects future patients from premature, ineffective and unsafe medications and treatments over the long run, but the process often takes many years;

(2) patients who have a terminal illness do 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) patients who have a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices;

(4) the use of available investigational drugs, biological products, and devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's health care provider and the patient's health care team, if applicable; and

(5) the decision to use an investigational drug, biological product, or device should be made with full awareness of the potential risks, benefits and consequences to the patient and the patient's family.

(b) It is the intent of the legislature to allow for terminally ill patients to use potentially life-saving investigational drugs, biological products, and devices.

Sec. 3. As used in sections 1 through 7, and amendments thereto, unless the context requires otherwise:

(a) (1) "Eligible patient" means a person who has:

(A) A terminal illness, attested to by the patient's treating physician;

(B) carefully considered all other treatment options approved by the United States food and drug administration;

(C) been unable to participate in a clinical trial for the terminal illness within 100 miles of the patient's home address, or not been accepted to the clinical trial within one week of completion of the clinical trial application process;

(D) received a recommendation from such patient's treating physician for an investigational drug, biological product, or device;

(E) given written, informed consent for the use of the investigational drug, biological product, or device, or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written, informed consent on the patient's behalf; and

(F) documentation from such patient's treating physician that such patient meets the requirements of this paragraph.

(2) "Eligible patient" does not include a person being treated as an inpatient in any hospital or ambulatory surgical center, as those terms are defined in K.S.A. 65-425, and amendments thereto.

recuperation

(b) "Investgational 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 yet been approved for general use by the United States food and drug administration and remains under investigation in a clinical trial approved by the United States food and drug administration.

Investigational

(c) "Terminal illness" means a disease or condition that, without life-sustaining procedures will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

(d) "Written, informed consent" means a written document signed by the patient and attested to by the patient's treating physician and a witness that, at a minimum:

(1) Explains the currently approved products and treatments for the disease or condition from which the patient suffers;

(2) attests to the fact that the patient concurs with the patient's treating physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(3) clearly identifies the specific proposed investigational drug, biological product, or device that the patient is seeking to use;

(4) describes the potentially best and worst outcomes of using the investigational drug, biological product, or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different or worse symptoms might result, and that death could be hastened by the proposed treatment, based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(5) makes clear that the patient's health insurer and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device;

(6) makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements;

(7) makes clear that in-home health care may be denied if treatment begins; and

(8) states that the patient understands that the patient is liable for all expenses consequent to the use of the investigational drug, biological product, or device, and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

Sec. 4. (a) A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients pursuant to sections 1 through 7, and amendments thereto. Nothing in sections 1 through 7, and amendments thereto, shall be construed to require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) [A manufacturer may:

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

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

[(c)] (1) A health insurance carrier may, but shall not be required to, provide coverage for the cost of an investigational drug, biological product, or device.

(2) An insurer may deny coverage to an eligible patient from the time the eligible patient begins use of the investigational drug, biological product, or device through a period not to exceed six months from the time the investigational drug, biological product, or device is no longer used by the eligible patient, except coverage may not be denied for a pre-existing condition and for coverage for benefits which commenced prior to the time the eligible patient begins use of such investigational drug, biological product, or device.

[(d)] (c) If a patient dies while being treated with an investigational drug, biological product, or device, the patient's heirs shall not be liable for any outstanding debt related to such treatment or lack of insurance due to such treatment.

Sec. 5. Notwithstanding any other law to the contrary, the board of healing arts shall not revoke, suspend or otherwise take any action against any individual holding a license issued pursuant to the Kansas healing arts act, K.S.A. 65-2801 et seq., and amendments thereto, based solely on such provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, as long as the recommendations are consistent with medical standards of care. Any action against an individual or entity's medicare certification

based solely on recommendations that a patient have access to an investigational drug, biological product, or device is prohibited.

Sec. 6. No state officer, employee or agent thereof shall block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

Sec. 7. Nothing in sections 1 through 7, and amendments thereto, shall be construed as creating a private cause of action against a manufacturer of an investigational drug, biological product, or device, or against any other person or entity involved in the care of an eligible patient using an investigational drug, biological product, or device for any injury suffered by the eligible patient resulting from the investigational drug, biological product, or device, so long as the manufacturer or other person or entity acted in accordance with the provisions of sections 1 through 7, and amendments thereto, except when such injury results from a failure to exercise reasonable care.

Sec. 8. This act shall take effect and be in force from and after its publication in the statute book.