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2016

LEGISLATURE OF NEBRASKA

ONE HUNDRED FOURTH LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 804

Introduced by Hilkemann, 4.

Read first time January 07, 2016

Committee: Health and Human Services

A BILL FOR AN ACT relating to public health and welfare; to adopt the Investigational Drug Use Act.

Be it enacted by the people of the State of Nebraska,

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Section 1. This act shall be known and may be cited as the Investigational Drug Use Act.

Sec. 2. For purposes of the Investigational Drug Use Act:

(1) Advanced illness means any progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with administration of federally approved and available treatments, and that, without life-sustaining procedures, would result in death;

(2) Eligible patient means a person who meets the requirements of section 3 of this act;

(3) Investigational drug, biological product, or device means any drug, biological product, or device that has successfully completed phase 1 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;

(4) Physician means any person who is licensed to practice medicine and surgery pursuant to the Medicine and Surgery Practice Act; and

(5) Written, informed consent means a writing which conforms to section 4 of this act.

Sec. 3. To be an eligible patient under the Investigational Drug Use Act, a person shall:

(1) Have an advanced illness, attested by the person's treating physician;

(2) Have considered all other treatment options approved by the United States Food and Drug Administration at the time;

(3) Have a recommendation from his or her treating physician for an investigational drug, biological product, or device;

(4) Give written, informed consent for the use of the investigational drug, biological product, or device; and

(5) Have documentation from his or her treating physician that he or

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she meets the requirements of the act.

Sec. 4. To be acceptable under the Investigational Drug Use Act, a written, informed consent shall consist of a signed writing executed by an eligible patient, or his or her parent or legal guardian if the eligible patient is a minor, and attested to by the eligible patient's treating physician, that:

(1) Explains the approved products and treatments available at that time for the disease or condition from which the patient suffers;

(2) Attests to the fact that the patient concurs with his or her treating physician that no treatment then approved by the United States Food and Drug Administration would likely 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 potential outcomes of using the investigational drug, biological product, or device. The description shall include any possibility of worsening symptoms and death hastened by the treatment;

(5) Contains a statement that the patient's health insurance carrier is 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 with the investigational drug, biological product, or device and that care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements; and

(7) Makes clear that the patient understands that he or she is liable for all expense consequent to the use of the investigational drug, biological product, or device.

Sec. 5. A manufacturer of an investigational drug, biological product, or device may make the treatment available pursuant to the Investigational Drug Use Act. An eligible patient may request the manufacturer's investigational drug, biological product, or device for

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treatment pursuant to the act. The act does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

Sec. 6. A manufacturer may provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

Sec. 7. If an eligible patient dies while being treated by an investigational drug, biological product, or device, the manufacturer may not seek reimbursement for any outstanding debt related to the treatment or lack of insurance due to the treatment from the eligible patient's or his or her caretaker's estate.

Sec. 8. No professional board may revoke, fail to renew, suspend, or take any action against a health care provider's license pursuant to the Uniform Credentialing Act based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. No entity responsible for medicare certification may take action against a health care provider's medicare certification based solely on the health care provider's recommendation regarding an investigational drug, biological product, or device.

Sec. 9. A treating physician who is in compliance with the requirements of the Investigational Drug Use Act may not be subject to arrest, prosecution, penalty, or denial of any right or privilege granted otherwise.

Sec. 10. No official, employee, or agent of this state may block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or recommendations consistent with medical standards of care from a licensed health care provider is not a violation of this section.

Sec. 11. The Investigational Drug Use Act does not create a private cause of action against a manufacturer of an investigational drug,

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biological product, or device or against another person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from treatment if the manufacturer or other person or entity has complied in good faith with the terms of the act and exercised reasonable care.