

LEGISLATURE OF NEBRASKA
ONE HUNDRED FIFTH LEGISLATURE
FIRST SESSION

LEGISLATIVE BILL 117

Introduced by Hilkemann, 4.

Read first time January 06, 2017

Committee: Health and Human Services

- 1 A BILL FOR AN ACT relating to public health and welfare; to adopt the
- 2 Investigational Drug Use Act.
- 3 Be it enacted by the people of the State of Nebraska,

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

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

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

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

11 (3) Health care provider has the same meaning as in section 71-7907;

12 (4) Investigational drug, biological product, or device means any
13 drug, biological product, or device that has successfully completed phase
14 one of a clinical trial but has not yet been approved for general use by
15 the United States Food and Drug Administration and remains under
16 investigation in a clinical trial approved by the United States Food and
17 Drug Administration;

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

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

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

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

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

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

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

1 (5) Have documentation from his or her treating physician that he or
2 she meets the requirements of the act; and

3 (6) Not be a patient receiving inpatient treatment in a hospital
4 licensed pursuant to the Health Care Facility Licensure Act.

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

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

12 (2) Attests to the fact that the patient concurs with his or her
13 treating physician that no treatment then approved by the United States
14 Food and Drug Administration would likely prolong the patient's life;

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

17 (4) Describes the potential outcomes, if known, of using the
18 investigational drug, biological product, or device. The description
19 shall include any possibility of worsening symptoms and death hastened by
20 the treatment;

21 (5) Contains a statement that the patient's health insurance carrier
22 is not obligated to pay for any care or treatments consequent to the use
23 of the investigational drug, biological product, or device;

24 (6) Makes clear that the patient's eligibility for hospice care may
25 be withdrawn if the patient begins curative treatment with the
26 investigational drug, biological product, or device and that care may be
27 reinstated if this treatment ends and the patient meets hospice
28 eligibility requirements; and

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

1 Sec. 5. A manufacturer of an investigational drug, biological
2 product, or device may make the treatment available pursuant to the
3 Investigational Drug Use Act. An eligible patient may request the
4 manufacturer's investigational drug, biological product, or device for
5 treatment pursuant to the act. The act does not require that a
6 manufacturer make available an investigational drug, biological product,
7 or device to an eligible patient.

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

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

16 Sec. 8. Neither the Director of Public Health of the Division of
17 Public Health nor the chief medical officer appointed pursuant to section
18 81-3115 may revoke, fail to renew, suspend, or take any action against a
19 health care provider's license pursuant to the Health Care Facility
20 Licensure Act or the Uniform Credentialing Act based solely on the health
21 care provider's recommendations to an eligible patient regarding access
22 to or treatment with an investigational drug, biological product, or
23 device. No entity responsible for certification under the medical
24 assistance program established pursuant to the Medical Assistance Act may
25 take action against a health care provider's certification based solely
26 on the health care provider's recommendation regarding an investigational
27 drug, biological product, or device.

28 Sec. 9. A treating physician while acting in good faith in the
29 course of his or her professional practice as authorized by the
30 Investigational Drug Use Act may not be subject to arrest, prosecution,
31 penalty, or denial of any right or privilege granted otherwise.

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

6 Sec. 11. The Investigational Drug Use Act does not create a private
7 cause of action against a manufacturer of an investigational drug,
8 biological product, or device or against another person or entity
9 involved in the care of an eligible patient using the investigational
10 drug, biological product, or device for any harm done to the eligible
11 patient resulting from treatment if the manufacturer or other person or
12 entity has complied in good faith with the terms of the act.