State of South Dakota

NINETIETH SESSION
LEGISLATIVE ASSEMBLY, 2015

651W0326

SENATE ENGROSSED NO. HB 1080 - 03/04/2015

Introduced by: Representatives Heinemann (Leslie), Deutsch, Hickey, Munsterman, and Stalzer and Senator Curd

FOR AN ACT ENTITLED, An Act to authorize the use of investigational treatments for patients under certain conditions and to restrict certain causes of action arising from investigational treatment.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. Terms used in this Act mean:

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

(2) "Investigational drug, biological product, or device," 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 United States Food and Drug Administration approved clinical trial;

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(3) "Physician," any person who is licensed pursuant to the provisions of chapter 36-4.

Section 2. For the purposes of this Act, the term, eligible patient, means a patient who meets all the following qualifications:

(1) Has an advanced illness, attested by the patient's treating physician;

(2) Has considered all other treatment options currently approved by the United States Food and Drug Administration;

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

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

(5) Has documentation from the patient's treating physician that the patient meets requirements pursuant to this Act.

Section 3. For purposes of this Act, the term, written, informed consent, consists of a signed writing executed by the patient, parent, or legal guardian, if the patient is a minor, or substitute informed consent from an appointed guardian, an attorney-in-fact, or a person with authority pursuant to chapter 34-12C, if the patient is incapacitated as defined in § 34-12C-1, and attested to by the treating physician, that:

(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 his or her treating physician that no current United States Food and Drug Administration approved treatment 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 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 patient meets hospice eligibility requirements; and

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

Section 4. A manufacturer of an investigational drug, biological product, or device may make the treatment available, and an eligible patient may request the manufacturer's investigational drug, biological product, or device for treatment pursuant to this Act. This Act does not require that a manufacturer make available an investigational drug, biological product, or devices to an eligible patient.

Section 5. A manufacturer may provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

Section 6. If a 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 patient's or caretaker's estate.

Section 7. No licensing board may revoke, fail to renew, suspend, or take any action against a health care provider's license pursuant to the provisions of chapter 36-4, 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.

Section 8. A treating physician who is in compliance with the requirements of this Act may not be subject to arrest or prosecution, penalty, or denial of any right or privilege granted otherwise.

Section 9. 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 a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

Section 10. This Act does not create a private cause of action against a manufacturer of an investigational drug, 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 is complying in good faith with the terms of this Act and exercised reasonable care.