2025 South Dakota Legislature

House Bill 1139

Introduced by: ***Representative*** *Andera*

An Act to allow individualized investigative treatments for patients with life-threatening or debilitating diseases or conditions.

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

Section 1. That § 34-51-1 be AMENDED:

34-51-1. Terms used in this chapter 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)~~ "Eligible facility," an institution operating under a federalwide assurance for the protection of human subjects, pursuant to 45 C.F.R. Part 46 (January 1, 2025);

(2) "Eligible patient," an individual who has:

(a) A disease or condition that is life-threatening or severely debilitating, as those terms are defined in 21 C.F.R § 312.81 (January 1, 2025), attested by the patient's treating physician;

(b) Considered all other treatment options approved by the United States Food and Drug Administration;

(c) Received a recommendation from the individual's treating physician for a general investigative treatment, or an individualized investigative treatment based on an analysis of the individual's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products, or metabolites;

(d) Given informed consent for the general or individualized investigative treatment; and

(e) Documentation from the individual's treating physician that the individual meets the requirements of this chapter;

(3) "~~Investigational drug, biological product, or device~~General investigative treatment," any drug, biological product, or device that has successfully completed phase ~~1~~ 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 ~~approved clinical trial~~;

(4) "Individualized investigative treatment," any drug, biological product, or device, from a manufacturer operating within an eligible facility, which is unique to and produced exclusively for an individual patient's use based on the patient's genetic profile; and

~~(3)~~(5) "Physician," any ~~person who is~~ individual licensed pursuant to ~~the provisions of~~ chapter 36-4.

Section 2. That § 34-51-3 be AMENDED:

34-51-3. ~~For purposes of this chapter, the term, written,~~ To receive a general or individualized investigative treatment, an eligible patient must give informed consent~~, consists of a signed writing executed~~.

For the purposes of this section, "informed consent," means a written document that:

(1) Is signed by the eligible patient~~,~~; the patient's 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~~;

(2) Is attested to by the treating physician~~, that:~~;

~~(1)~~(3) Explains the currently approved products and treatments for the disease or condition from which the patient suffers;

~~(2)~~(4) ~~Attests to the fact that the patient concurs with his or her~~ Contains the patient's concurrence with the treating physician that no ~~current~~ treatment approved by the United States Food and Drug Administration ~~approved treatment~~ would likely prolong the patient's life;

~~(3)~~(5) Clearly identifies the specific proposed ~~investigational drug, biological product, or device~~ general or individualized investigative treatment that the patient is seeking to use;

~~(4)~~(6) Describes, based on the treating physician's knowledge of the general or individualized investigative treatment and the patient's condition, the potential outcomes of using ~~investigational drug, biological product, or device. The description shall include~~ the treatment, and any possibility of worsening symptoms ~~and~~ or death hastened by the treatment;

~~(5)~~(7) ~~Contains a statement~~ States that the~~ patient's~~:

(a) 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~~ general or individualized investigative treatment; and

(b) Patient understands that the patient is liable for all expenses consequent to the use of the treatment; and

~~(6)~~(8) ~~Makes clear~~ States 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~~ general or individualized investigative treatment, 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~~.

Section 3. That § 34-51-4 be AMENDED:

34-51-4. A manufacturer of~~ an investigational drug, biological product, or device~~ a general investigative treatment, or a manufacturer of an individualized investigative treatment operating within an eligible facility, may make the treatment available~~, and an~~ to an eligible patient, with or without compensation. An eligible facility, or a manufacturer operating within an eligible facility, may require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the individualized investigative treatment.

An eligible patient may request~~ the manufacturer's investigational drug, biological product, or device for~~ a general or individualized investigative treatment pursuant to this chapter.

This chapter does not require~~ that~~ a manufacturer or eligible facility to make available~~ an investigational drug, biological product, or devices~~ the general or individualized investigative treatment to an eligible patient.

Section 4. That § 34-51-6 be AMENDED:

34-51-6. If a patient dies while ~~being treated by an investigational drug, biological product, or device,~~ receiving a general or individualized investigative treatment, the manufacturer or eligible facility 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 5. That § 34-51-7 be AMENDED:

34-51-7. No licensing board may revoke, fail to renew, suspend, or take any action against a ~~health care provider's~~ physician's license pursuant to ~~the provisions of~~ chapter 36-4, based solely on the ~~health care provider's~~ physician's recommendations to an eligible patient regarding access to or ~~treatment with an investigational drug, biological product, or device~~ receipt of a general or individualized investigative treatment. No entity responsible for ~~Medicare~~ medicare certification may take action against a ~~health care provider's Medicare~~ physician's medicare certification based solely on the ~~health care provider's~~ physician's recommendation regarding ~~an investigational drug, biological product, or device~~ a general or individualized investigative treatment.

Section 6. That § 34-51-9 be AMENDED:

34-51-9. 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~~ a general or individualized investigative treatment. 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 7. That § 34-51-10 be AMENDED:

34-51-10. This chapter does not create a private cause of action against a manufacturer of ~~an investigational drug, biological product, or device,~~ a general or individualized investigative treatment, or against another person or entity involved in the care of an eligible patient ~~using~~ receiving the ~~investigational drug, biological product, or device~~ treatment, 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 chapter and exercised reasonable care.

Section 8. That a NEW SECTION be added to chapter 34-51:

Nothing in this chapter requires:

(1) A governmental agency to pay any costs associated with the use, care, or treatment of an eligible patient with an individualized investigative treatment;

(2) A health plan, health carrier, or third-party administrator to provide coverage for the cost of an individualized investigative treatment or other costs of services related to the treatment; or

(3) A health care facility, licensed in accordance with chapter 34-12, to provide new or additional services, unless approved by the facility.

Section 9. That § 34-51-2 be REPEALED.

~~For the purposes of this chapter, 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 the 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 chapter.~~

Section 10. That § 34-51-5 be REPEALED.

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