2025 South Dakota Legislature

House Bill 1139

ENROLLED

AN ACT

ENTITLED 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) "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) "General investigative treatment," any 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;

(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

(5) "Physician," any individual licensed pursuant to chapter 36-4.

Section 2. That § 34-51-3 be AMENDED:

34-51-3. To receive a general or individualized investigative treatment, an eligible patient must give informed consent.

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 an appointed guardian, attorney-in-fact, or person with authority pursuant to chapter 34-12C, if the patient is incapacitated as defined in § 34-12C-1;

(2) Is attested to by the treating physician;

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

(4) Contains the patient's concurrence with the treating physician that no treatment approved by the United States Food and Drug Administration would likely prolong the patient's life;

(5) Clearly identifies the specific proposed general or individualized investigative treatment that the patient is seeking to use;

(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 the treatment, and any possibility of worsening symptoms or death hastened by the treatment;

(7) States that the:

(a) Patient's health insurance carrier is not obligated to pay for any care or treatments consequent to the use of the 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

(8) States that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the general or individualized investigative treatment, and that care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

Section 3. That § 34-51-4 be AMENDED:

34-51-4. A manufacturer of a general investigative treatment, or a manufacturer of an individualized investigative treatment operating within an eligible facility, may make the treatment available 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 a general or individualized investigative treatment pursuant to this chapter.

This chapter does not require a manufacturer or eligible facility to make available 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 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 physician's license pursuant to chapter 36-4, based solely on the physician's recommendations to an eligible patient regarding access to or receipt of a general or individualized investigative treatment. No entity responsible for medicare certification may take action against a physician's medicare certification based solely on the physician's recommendation regarding 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 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 a general or individualized investigative treatment, or against another person or entity involved in the care of an eligible patient receiving the 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.

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

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

I certify that the attached Act originated in the:

House as Bill No. 1139

_____
Chief Clerk

_____
Speaker of the House

Attest:

_____
Chief Clerk

_____
President of the Senate

Attest:

_____
Secretary of the Senate

House Bill No. 1139
File No. ____
Chapter No. _____

Received at this Executive Office
this _____ day of _____,

2025 at _____M.

By _____
for the Governor

The attached Act is hereby
approved this _____ day of
_____, A.D., 2025

_____
Governor

STATE OF SOUTH DAKOTA,

ss.

Office of the Secretary of State

Filed _____, 2025
at _____ o'clock __M.

_____
Secretary of State

By _____
Asst. Secretary of State