



2022 South Dakota Legislature

House Bill 1228

Introduced by: **Representative** Haugaard

1 **An Act to expand the ability for patients to seek investigational drugs, biological**
 2 **products, or devices.**

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

4 **Section 1. That § 34-51-1 be AMENDED:**

5 **34-51-1.** Terms used in this chapter mean:

- 6 (1) "Advanced illness," any progressive disease, medical, or surgical condition that
 7 entails significant functional impairment, that is not considered by a treating
 8 physician to be reversible even with administration of current federally approved
 9 and available treatments, and that without life sustaining procedures, would result
 10 in death;
- 11 (2) "Investigational drug, biological product, or device," any drug, biological product,
 12 or device that has successfully completed phase 1 of a clinical trial but has not yet
 13 been approved for general use by the United States Food and Drug Administration
 14 and remains under investigation in a United States Food and Drug Administration
 15 approved clinical trial;
- 16 (3) "Physician," any person who is licensed pursuant to the provisions of chapter 36-4;
- 17 (4) "Serious illness," any disease, medical condition, or surgical condition that entails
 18 extreme pain, permanent disability, or a condition that is considered by a treating
 19 physician to not be reversible even with administration of current federally
 20 approved and available treatments.

21 **Section 2. That § 34-51-2 be AMENDED:**

22 **34-51-2.** For the purposes of this chapter, the term, eligible patient, means a
 23 patient who meets all the following qualifications:

- 24 (1) Has an advanced illness or serious illness, attested by the patient's treating
 25 physician;

- 1 (2) Has considered all other treatment options currently approved by the United States
2 Food and Drug Administration;
- 3 (3) Has received a recommendation from the patient's treating physician for an
4 investigational drug, biological product, or device;
- 5 (4) Has given written, informed consent for the use of the investigational drug,
6 biological product, or device; and
- 7 (5) Has documentation from the patient's treating physician that the patient meets
8 requirements pursuant to this chapter.

9 **Section 3. That § 34-51-3 be AMENDED:**

10 **34-51-3.** For purposes of this chapter, the term, written, informed consent,
11 ~~consists of~~ means a signed writing executed by the patient, parent, or legal guardian, if
12 the patient is a minor, or substitute informed consent from an appointed guardian, an
13 attorney-in-fact, or a person with authority pursuant to chapter 34-12C, if the patient is
14 incapacitated as defined in § 34-12C-1 or has otherwise relinquished their personal
15 authority to their attorney-in-fact, and attested to by the treating physician, that:

- 16 (1) Explains the currently approved products and treatments for the disease or
17 condition from which the patient suffers;
- 18 (2) Attests to the fact that the patient concurs with his or her treating physician that
19 no current United States Food and Drug Administration approved or alternative
20 treatment would likely prolong possibly:
 - 21 (a) Prolong the patient's life, in the case of advanced illness; or
 - 22 (b) Improve the patient's prognosis, in the case of serious illness;
- 23 (3) Clearly identifies the specific proposed investigational drug, biological product, or
24 device that the patient is seeking to use;
- 25 (4) Describes the potential outcomes of using investigational drug, biological product,
26 or device. The description shall include any possibility of worsening symptoms and
27 death hastened by the treatment;
- 28 (5) Contains a statement that the patient's health insurance carrier is not obligated to
29 pay for any care or treatments consequent to the use of the investigational drug,
30 biological product, or device;
- 31 (6) Makes clear that, in the case of advanced illness, the patient's eligibility for hospice
32 care may be withdrawn if the patient begins curative treatment with the
33 investigational drug, biological product, or device and that care may be reinstated
34 if this treatment ends and patient meets hospice eligibility requirements; and

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