

Introduced by

Senators Mathern, Wanzek, Heckaman

Representatives Oversen, Pollert, Glasheim

1 A BILL for an Act to create and enact chapter 23-48 of the North Dakota Century Code, relating
2 to the use of experimental drugs.

3 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

4 **SECTION 1.** Chapter 23-48 of the North Dakota Century Code is created and enacted as
5 follows:

6 **23-48-01. Definitions.**

7 As used in this chapter, unless the context otherwise requires:

8 1. a. "Eligible patient" means an individual who:

- 9 (1) Has a terminal illness that is attested to by the patient's treating physician;
10 (2) Considered all other treatment options currently approved by the United
11 States food and drug administration;
12 (3) If there is a clinical trial for the terminal illness within one hundred miles of
13 the patient's home address for the terminal illness, is unable to participate in
14 the clinical trial or within one week of completion of the clinical trial
15 application process is not accepted to the clinical trial;
16 (4) Has a recommendation from the patient's treating physician for an
17 investigational drug, biological product, or device;
18 (5) Has given written, informed consent for the use of the investigational drug,
19 biological product, or device or, if the patient is a minor or lacks the mental
20 capacity to provide informed consent, a parent or legal guardian has given
21 written, informed consent on the patient's behalf; and
22 (6) Has documentation by the patient's treating physician the patient meets the
23 requirements of this subdivision.

- 1 b. The term does not include an individual treated as an inpatient in a hospital
2 licensed under chapter 23-16.
- 3 2. "Investigational drug, biological product, or device" means a drug, biological product,
4 or device that has successfully completed phase one of a clinical trial but has not yet
5 been approved for general use by the United States food and drug administration and
6 remains under investigation in a United States food and drug administration-approved
7 clinical trial.
- 8 3. "Terminal illness" means a disease that, without life-sustaining procedures, will soon
9 result in death or a state of permanent unconsciousness from which recovery is
10 unlikely.
- 11 4. "Written, informed consent" means a written document signed by the patient or the
12 patient's parent or legal guardian and attested to by the patient's treating physician
13 and by a witness which:
- 14 a. Explains the currently approved products and treatments for the terminal illness
15 from which the patient suffers;
- 16 b. Attests to the fact the patient concurs with the patient's treating physician in
17 believing that all currently approved and conventionally recognized treatments
18 are unlikely to prolong the patient's life;
- 19 c. Identifies the specific proposed investigational drug, biological product, or device
20 the patient is seeking to use;
- 21 d. Describes the potentially best and worst outcomes of using the investigational
22 drug, biological product, or device with a realistic description of the most likely
23 outcome, including the possibility that new, unanticipated, different, or worse
24 symptoms might result, and that death could be hastened by the proposed
25 treatment, based on the treating physician's knowledge of the proposed
26 treatment in conjunction with an awareness of the patient's condition;
- 27 e. States the patient's health insurer and provider are not obligated to pay for any
28 care or treatments consequent to the use of the investigational drug, biological
29 product, or device;

- 1 f. States the patient's eligibility for hospice care may be withdrawn if the patient
2 begins curative treatment and that hospice care may be reinstated if the curative
3 treatment ends and the patient meets hospice eligibility requirements;
4 g. States in-home health care may be denied if treatment begins; and
5 h. Attests that the patient understands the patient is liable for all expenses
6 consequent to the use of the investigational drug, biological product, or device,
7 and that this liability may extend to the patient's estate, unless a contract
8 between the patient and the manufacturer of the drug, biological product, or
9 device states otherwise.

10 **23-48-02. Drug manufacturers - Availability of investigational drugs, biological**
11 **products, or devices - Costs - Insurance coverage.**

- 12 1. A manufacturer of an investigational drug, biological product, or device may make
13 available the manufacturer's investigational drug, biological product, or device to an
14 eligible patient pursuant to this chapter. This chapter does not require that a
15 manufacturer make available to an eligible patient an investigational drug, biological
16 product, or device.
- 17 2. A manufacturer may:
- 18 a. Provide to an eligible patient an investigational drug, biological product, or device
19 without receiving compensation; or
- 20 b. Require an eligible patient to pay the costs of, or the costs associated with, the
21 manufacture of the investigational drug, biological product, or device.
- 22 3. a. This chapter does not expand a health insurance mandate provided for under
23 chapter 26.1-36.
- 24 b. An insurer may provide coverage for the cost of an investigational drug, biological
25 product, or device.
- 26 c. An insurer may deny coverage to an eligible patient from the time the eligible
27 patient begins use of the investigational drug, biologic product, or device through
28 a period not to exceed six months from the time the investigational drug, biologic
29 product, or device is no longer used by the eligible patient. However, under this
30 subdivision, coverage may not be denied for a preexisting condition or for

1 coverage for benefits that commenced before the time the eligible patient began
2 use of the drug, biologic product or device.

3 4. If an eligible patient dies while being treated by an investigational drug, biological
4 product, or device, the eligible patient's heirs are not liable for any outstanding debt
5 related to the treatment or lack of insurance due to the treatment.

6 **23-48-03. Action against health care provider's license or medicare certification**
7 **prohibited.**

8 Notwithstanding any other law, a licensing board may not revoke, fail to renew, suspend, or
9 take any action against a health care provider's license issued in this state, based solely on the
10 health care provider's recommendations to an eligible patient regarding access to or treatment
11 with an investigational drug, biological product, or device, if the recommendations are
12 consistent with medical standards of care. Action against a health care provider's medicare
13 certification based solely on the health care provider's recommendation that a patient have
14 access to an investigational drug, biological product, or device is prohibited.

15 **23-48-04. Access to investigational drugs, biological products, and devices.**

16 An official, employee, or agent of this state may not block or attempt to block an eligible
17 patient's access to an investigational drug, biological product, or device. Counseling, advice, or
18 a recommendation consistent with medical standards of care from a licensed health care
19 provider is not a violation of this section. This section does not require payment for experimental
20 drugs under this state's medical assistance program or from other payer sources.

21 **23-48-05. Cause of action not created.**

22 This chapter does not create a private cause of action against a manufacturer of an
23 investigational drug, biological product, or device or against any other person involved in the
24 care of an eligible patient using the investigational drug, biological product, or device, for any
25 harm done to the eligible patient resulting from the investigational drug, biological product, or
26 device, if the manufacturer or other person complied in good faith with the terms of this chapter.
27 However, this chapter does not limit a private cause of action against a manufacturer or other
28 person if there was a failure to exercise reasonable care.