

**FIRST ENGROSSMENT  
with House Amendments  
ENGROSSED SENATE BILL NO. 2259**

Introduced by

Senators Mathern, Wanzek, Heckaman

Representatives Oversen, Pollert, Glassheim

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; and to provide for a notification by the secretary of state.

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

25           **23-48-03. Action against health care provider's license or medicare certification**  
26 **prohibited.**

27           Notwithstanding any other law, a licensing board may not revoke, fail to renew, suspend, or  
28 take any action against a health care provider's license issued in this state, based solely on the  
29 health care provider's recommendations to an eligible patient regarding access to or treatment  
30 with an investigational drug, biological product, or device, if the recommendations are  
31 consistent with medical standards of care. Action against a health care provider's medicare

1 certification based solely on the health care provider's recommendation that a patient have  
2 access to an investigational drug, biological product, or device is prohibited.

3 **23-48-04. Access to investigational drugs, biological products, and devices.**

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

9 **23-48-05. Cause of action not created.**

10 This chapter does not create a private cause of action against a manufacturer of an  
11 investigational drug, biological product, or device or against any other person involved in the  
12 care of an eligible patient using the investigational drug, biological product, or device, for any  
13 harm done to the eligible patient resulting from the investigational drug, biological product, or  
14 device, if the manufacturer or other person complied in good faith with the terms of this chapter.  
15 However, this chapter does not limit a private cause of action against a manufacturer or other  
16 person if there was a failure to exercise reasonable care.

17 **SECTION 2. NOTIFICATION BY SECRETARY OF STATE.** The secretary of state shall  
18 notify the federal food and drug administration and the North Dakota congressional delegation  
19 of this bill by sending a copy of this bill upon filing with the secretary of state.