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Sixty-fourth
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT
with House Amendments
ENGROSSED SENATE BILL NO. 2259

Introduced by

Senators Mathern, Wanzek, Heckaman

Representatives Oversen, Pollert, Glassheim

A BILL for an Act to create and enact chapter 23-48 of the North Dakota Century Code, relating to the use of experimental drugs; and to provide for a notification by the secretary of state.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

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

23-48-01. Definitions.

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

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

b. The term does not include an individual treated as an inpatient in a hospital licensed under chapter 23-16.

2. "Investigational drug, biological product, or device" means a 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 United States food and drug administration-approved clinical trial.

3. "Terminal illness" means a disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

4. "Written, informed consent" means a written document signed by the patient or the patient's parent or legal guardian and attested to by the patient's treating physician and by a witness which:

a. Explains the currently approved products and treatments for the terminal illness from which the patient suffers;

b. Attests to the fact the patient concurs with the patient's treating physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

c. Identifies the specific proposed investigational drug, biological product, or device the patient is seeking to use;

d. Describes the potentially best and worst outcomes of using the investigational drug, biological product, or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result, and that death could be hastened by the proposed treatment, based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

e. States the patient's health insurer and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device;

f. States the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and that hospice care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements;

g. States in-home health care may be denied if treatment begins; and

h. Attests that the patient understands the patient is liable for all expenses consequent to the use of the investigational drug, biological product, or device, and that this liability may extend to the patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

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

1. A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to an eligible patient pursuant to this chapter. This chapter does not require that a manufacturer make available to an eligible patient an investigational drug, biological product, or device.

2. A manufacturer may:

   a. Provide to an eligible patient an investigational drug, biological product, or device without receiving compensation; or

   b. Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

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

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

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

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

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

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

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

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

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