CHAPTER 23-48
EXPERIMENTAL DRUGS

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.


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.