AN ACT relating to use of experimental treatments for terminal illnesses.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

As used in Sections 1 to 9 of this Act:

(1) "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, protein other than a chemically synthesized polypeptide, allergenic product or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings;

(2) "Device" has the same meaning as in KRS 217.015;

(3) "Drug" has the same meaning as in KRS 217.015;

(4) "Eligible patient" means an individual who meets the requirements of Section 3 of this Act;

(5) "Health facility" has the same meaning as in KRS 216B.015;

(6) "Health care provider" means a licensed physician, a licensed advanced practice registered nurse, or a licensed physician assistant;

(7) "Investigational drug, biological product, or device" means a drug, biological product, or device that:

(a) Has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration; and

(b) Remains under investigation in a United States Food and Drug Administration-approved clinical trial;

(8) "Terminal illness" means a progressive disease or a medical or surgical condition that:

(a) Entails significant functional impairment;

(b) Is not considered by a treating health care provider to be reversible even with administration of a treatment currently approved by the United States Food and Drug Administration; and

(c) Without life-sustaining procedures, will result in death; and

(9) "Written informed consent" means a written document that meets the requirements of Section 4 of this Act.

➔SECTION 2. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

(1) A manufacturer of an investigational drug, biological product, or device may make the investigational drug, biological product, or device available to an eligible patient who has requested it pursuant to Sections 1 to 9 of this Act.

(2) The manufacturer may:

(a) Provide an investigational drug, biological product, or device to an eligible patient 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) A manufacturer shall not be required to make an investigational drug, biological product, or device available to an eligible patient.

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

A patient shall be eligible for treatment with an investigational drug, biological product, or device if the patient has:

(1) A terminal illness that is attested to by the patient's treating health care provider;

(2) Considered all other treatment options currently approved by the United States Food and Drug Administration;

(3) Received a recommendation from the patient's treating health care provider for

an investigational drug, biological product, or device;

(4) Given written informed consent for the use of the investigational drug, biological product, or device; and

(5) Has documentation from the treating health care provider that the patient meets the requirements of this section.

➔SECTION 4. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

(1) A patient or a patient's legal guardian shall provide written informed consent for treatment with an investigational drug, biological product, or device.

(2) At a minimum, the written informed consent shall include:

(a) An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers;

(b) An attestation that the patient concurs with the treating health care providers' belief that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(c) Clear identification of the specific investigational drug, biological product, or device that the patient is seeking to use;

(d) A description of the potentially best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome;

(e) A statement that the patient's health plan or third-party administrator and provider shall not be obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device unless they are specifically required to do so by law or contract;

(f) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the

treatment ends and the patient meets hospice eligibility requirements; and

(g) A statement that the patient understands that the patient shall be liable for all expenses related to the use of the investigational drug, biological product, or device and that the liability for expenses extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

(3) The description of potential outcomes required under subsection (2)(d) of this section shall:

(a) Include the possibility that new, unanticipated, different, or worse symptoms may result and that the proposed treatment may hasten death; and

(b) Be based on the treating health care provider's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(4) The written informed consent shall be:

(a) Signed by:

1. The patient;

2. A parent or legal guardian, if the patient is a minor; or

3. A legal guardian, if a guardian has been appointed for the patient; and

(b) Attested to by the patient's treating health care provider and a witness.

➔SECTION 5. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

(1) Sections 1 to 9 of this Act shall not:

(a) Expand the coverage required of an insurer;

(b) Affect the requirements for insurance coverage of routine patient costs for patients involved in approved cancer clinical trials;

(c) Require a health plan, third-party administrator, or governmental agency to

pay costs associated with the use, care, or treatment of an eligible patient with an investigational drug, biological product, or device; or

(d) Require a hospital or health facility to provide new or additional services.

(2) A health plan, third-party administrator, or governmental agency may provide coverage for the cost of an investigational drug, biological product, or device or the cost of services related to the use of an investigational drug, biological product, or device under Sections 1 to 9 of this Act.

(3) A hospital or health facility may approve the use of an investigational drug, biological product, or device in the hospital or health facility.

➔SECTION 6. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

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

➔SECTION 7. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

(1) A licensing board shall not revoke, fail to renew, suspend, or take any action against a licensed health care provider 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.

(2) The Cabinet for Health and Family Services shall not take action against a health care provider's Medicare or Medicaid certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

➔SECTION 8. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

(1) An official, employee, or agent of the Commonwealth of Kentucky shall not block

or attempt to block an eligible patient's access to an investigational drug, biological product, or device.

(2) Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider shall not be considered a violation of this section.

➔SECTION 9. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

A manufacturer of an investigational drug, biological product, or device, a pharmacist, a health facility, a health care provider, or a person or entity involved in the care of an eligible patient using an investigational drug, biological product, or device shall be immune from civil or criminal liability for any harm done to the eligible patient resulting from use of an investigational drug, biological product, or device if the manufacturer, pharmacist, health facility, health care provider, or other person or entity is complying in good faith with the terms of Sections 1 to 9 of this Act and the harm to the eligible patient did not result from the gross negligence or willful or wanton misconduct of the manufacturer, pharmacist, health facility, health care provider, or other person or entity.