AN ACT relating to the use of experimental treatments for life-threatening or severely debilitating illness.

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:

(1) As used in this section:

(a) "Eligible facility" means an institution operating under Federalwide Assurance for the Protection of Human Subjects in accordance with 45 C.F.R. pt. 46 and 42 U.S.C. sec. 289(a);

(b) "Eligible patient" means an individual who has:

1. A life-threatening or severely debilitating illness as attested by the patient's treating physician;

2. In consultation with the patient's treating physician, considered all other treatment options currently approved by the United States Food and Drug Administration;

3. Received a recommendation from the patient's treating physician for the use of an individualized investigational drug, biological product, or device for treatment of the life-threatening or severely debilitating illness;

4. a. Provided written informed consent to the use of the individualized investigational drug, biological product, or device for treatment of the life-threatening or severely debilitating illness; or

b. If the individual is a minor or is otherwise incapable of providing informed consent, the parent or legal guardian has given informed consent in writing to the use of the individualized investigational drug, biological product, or device; and

5. Documentation from the patient's treating physician that the individual meets all the criteria for an eligible patient, including an attestation from the treating physician that the treating physician was consulted in the creation of the written, informed consent required under this section;

(c) "Individualized investigational drug, biological product, or device" means a drug, biological product, or device that is unique and produced exclusively for use for an individual patient, based on the patient's own genetic profile, including individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines;

(d) "Institution" has the same meaning as in 45 C.F.R. sec. 46.102(f);

(e) "Life-threatening or severely debilitating illness" has the same meaning as "life-threating" and "severely debilitating" in 21 C.F.R. sec. 312.81; and

(f) "Written, informed consent" means a written document that:

1. Is signed by:

a. An eligible patient;

b. If the patient is a minor, by a parent or legal guardian; or

c. If the patient is incapacitated, by a designated health care agent pursuant to a health care power of attorney; and

2. Includes the following:

a. An explanation of the currently approved products and treatments for the eligible patient's life-threatening or severely debilitating illness;

b. An attestation that the eligible patient concurs with the treating physician in believing that all currently approved treatments are unlikely to prolong the eligible patient's life;

c. Clear identification of the specific individualized investigational

drug, biological product, or device proposed for treatment of the eligible patient's terminal illness;

d. A description of the potentially best and worst outcomes resulting from use of the individualized investigational drug, biological product, or device to treat the eligible patient's life-threatening or severely debilitating illness, along with a realistic description of the most likely outcome. The description shall be based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the eligible patient's life-threatening or severely debilitating illness and shall include a statement acknowledging that new, unanticipated, different, or worse symptoms might result from, and that death could be hastened by, the proposed treatment;

e. A statement that eligibility for hospice care may be withdrawn if the eligible patient begins treatment of the life-threatening or severely debilitating illness with an individualized investigational drug, biological product, or device and that hospice care may be reinstated if such treatment ends and the eligible patient meets hospice eligibility requirements;

f. A statement that the eligible patient's health benefit plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the individualized investigational drug, biological product, or device, unless specifically required to do so by law or contract;

g. A statement that the eligible patient understands that he or she is liable for all expenses consequent to the use of the individualized investigational drug, biological product, or device and that this

liability extends to the eligible patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise; and

h. A statement that the eligible patient or, for an eligible patient who is a minor or lacks capacity to provide informed consent, that the parent or legal guardian consents to the use of the individualized investigational drug, biological product, or device for treatment of the life-threatening or severely debilitating illness.

(2) (a) A manufacturer operating within an eligible facility in accordance with all applicable federal laws may make available to an eligible patient, and an eligible patient may request, the manufacturer's individualized investigational drug, biological product, or device from an eligible facility or manufacturer operating within an eligible facility.

(b) A manufacturer of an individualized investigational drug, biological product, or device may:

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

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

(c) Nothing in this subsection shall be construed to require a manufacturer of an individualized investigational drug, biological product, or device to make the individualized investigational drug, biological product, or device available to an eligible patient.

(3) If an eligible patient dies while being treated with an individualized investigational drug, biological product, or device, the eligible patient's heirs

shall not be liable for any outstanding debt related to the treatment, including any costs attributed to lack of insurance coverage for the treatment.

(4) (a) A licensing board shall not revoke, fail to renew, suspend, or take any other disciplinary action against a health care provider licensed in Kentucky based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an individualized investigational drug, biological product, or device.

(b) 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 individualized investigational drug, biological product, or device.

(5) (a) An official, employee, or agent of the Commonwealth of Kentucky shall not block or attempt to block an eligible patient's access to an individualized investigational drug, biological product, or device.

(b) Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider or denial of coverage by the Kentucky Medicaid program shall not constitute a violation of this subsection.

(6) A private right of action may not be brought against a manufacturer of an individualized investigational drug, biological product, or device, or against any other person or entity involved in the care of an eligible patient using an individualized investigational drug, biological product, or device, for any harm caused to the eligible patient resulting from use of the individualized investigational drug, biological product, or device as long as the manufacturer or other person or entity has made a good-faith effort to comply with the provisions of this section and has exercised reasonable care in actions undertaken in accordance with this section.

(7) This section shall be not construed to:

(a) Expand the coverage required to be offered or provided by a health insurance policy, plan, certificate, or contract;

(b) Affect any requirement for a health insurance policy, plan, certificate, or contract to provide coverage for routine patient costs for patients involved in approved cancer clinical trials;

(c) Require an insurer, third-party administrator, or governmental agency to pay costs associated with the treatment of an eligible patient with an individualized investigational drug, biological product, or device; or

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