WEST VIRGINIA CODE CHAPTER 16 ARTICLE 51

WV Legislature

§16-51-1. Short title.

This article shall be known and may be cited as the Ben Price Right to Try Act.

WV Legislature

§16-51-2. Legislative findings.

[Repealed.]

WV Legislature

§16-51-3. Definitions.

For the purposes of this article:

(1) “Eligible patient” means a person who has:

(A) A life-threatening or severely debilitating illness, attested to by a treating physician.

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

(C) Received a recommendation from his or her physician for an investigational drug, biological product or device;

(D) 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

(E) Documentation from his or her physician that he or she meets the requirements of this subdivision.

(2) “Eligible patient” does not include a person being treated as an inpatient in a hospital licensed or certified pursuant to §16-5B-1 *et seq*.

(3) “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 or a drug, biological product, or device that is unique and produced exclusively for use for an individual patient, based on their own genetic profile, including individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.

(4) Life-threatening or severely debilitating illness means as those terms are defined in 21 C.F.R. § 312.81.

(5) “Written, informed consent” means a written document signed by the patient and attested to by the patient’s physician and a witness that, at a minimum:

(A) Explains the currently approved products and treatments for the disease or condition from which the patient suffers;

(B) Attests to the fact that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient’s life;

(C) Clearly identifies the specific proposed investigational drug, biological product or device

WV Legislature

that 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 physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(E) Makes clear that the patient's health insurer and provider may not be obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product or device;

(F) Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements;

(G) Makes clear that in-home health care may be denied if treatment begins; and

(H) States that the patient understands that he or she may be liable for all expenses consequent to the use of the investigational drug, biological product or device, and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product or device states otherwise.

WV Legislature

§16-51-4. Drug manufacturers; availability of investigational drugs, biological products or devices; costs; insurance coverage.

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

(b) A manufacturer may:

(1) Provide an investigational drug, biological product or device to an eligible patient without receiving compensation; or

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

(c) Nothing in this article expands the coverage required by article fifteen, chapter thirty-three of this code.

(d) A health insurance carrier may, but is not required by this article to, provide coverage for the cost of an investigational drug, biological product or device.

(e) An insurer may deny coverage to an eligible patient from the time the eligible patient begins use of the investigational drug, biologic product or device through a period not to exceed six months from the time the investigational drug, biologic product or device is no longer used by the eligible patient; except that coverage may not be denied for a preexisting condition and for coverage for benefits which commenced prior to the time the eligible patient begins use of such drug, biologic product or device.

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

WV Legislature

§16-51-5. 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 pursuant to chapter thirty of this code 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 as long as 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.

WV Legislature

§16-51-6. Access to investigational drugs, biological products and devices.

An official, employee or agent of this state shall 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.

WV Legislature

§16-51-7. No cause of action created.

This article does not create a private cause of action against a manufacturer of an investigational drug, biological product or device, against a health care provider as defined in section two, article seven-b, chapter fifty-five of this Code, or against any other person or entity 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, so long as the manufacturer, health care provider, or other person or entity is complying in good faith with the terms of this article.

WV Legislature

§16-51-8. Effect on health care coverage.

Nothing in this article affects the mandatory health care coverage for participation in clinical trials pursuant to section two, article twenty-five-f, chapter thirty-three of this code.

WV Legislature