WEST VIRGINIA LEGISLATURE

2025 REGULAR SESSION

Committee Substitute

for

House Bill 2410

By Delegates Hornby, Chiarelli, Horst, Crouse,

Maynor, Willis, and Ward

[Originating in the Standing Committee on Health and

Human Resources; Reported on March 24, 2025]

A BILL to amend and reenact §16-51-1 of the Code of West Virginia, 1931, as amended, relating to the right to try individualized treatments; and defining terms.

Be it enacted by the Legislature of West Virginia:

ARTICLE 51. RIGHT-TO-TRY ACT.

§16-51-3. Definitions.

For the purposes of this article:

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

(A) ~~A terminal illness attested to by the patient’s treating physician;~~ 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) ~~Been unable to participate in a clinical trial for the terminal illness within one hundred miles of the patient’s home address for the terminal illness, or not been accepted to the clinical trial within one week of completion of the clinical trial application process;~~

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

~~(E)~~ (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

~~(F)~~ (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- 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) ~~"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.~~ 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 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.

NOTE: The purpose of this bill is to permit access to individualized treatments for eligible patients.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.