

# **WEST VIRGINIA LEGISLATURE**

**2025 REGULAR SESSION**

**ENGROSSED**

**Committee Substitute**

**for**

**Committee Substitute**

**for**

**House Bill 2410**

By Delegates Hornby, Chiarelli, Horst, Crouse,

Maynor, Willis, and Ward

[Reported March 28, 2025, from the Committee on

the Judiciary]



1 A BILL to amend and reenact §16-51-3 of the Code of West Virginia, 1931, as amended; and to  
2 repeal §16-51-2, 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.**

**§16-51-2. Legislative findings.**

1 [Repealed.]

**§16-51-3. Definitions.**

1 For the purposes of this article:

2 (1) "Eligible patient" means a person who has:

3 (A) ~~A terminal illness attested to by the patient's treating physician; A life-threatening or~~  
4 severely debilitating illness, attested to by a treating physician.

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

7 (C) ~~Been unable to participate in a clinical trial for the terminal illness within one hundred~~  
8 ~~miles of the patient's home address for the terminal illness, or not been accepted to the clinical trial~~  
9 ~~within one week of completion of the clinical trial application process;~~

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

12 (E) ~~(D)~~ Given written, informed consent for the use of the investigational drug, biological  
13 product or device or, if the patient is a minor or lacks the mental capacity to provide informed  
14 consent, a parent or legal guardian has given written, informed consent on the patient's behalf;  
15 and

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

18 (2) "Eligible patient" does not include a person being treated as an inpatient in a hospital  
19 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;

46           (F) Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient  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

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

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