

# **WEST VIRGINIA LEGISLATURE**

## **2025 REGULAR SESSION**

**Introduced**

### **Senate Bill 594**

By Senator Rucker

[Introduced February 25, 2025; referred  
to the Committee on Health and Human Resources;  
and then to the Committee on the Judiciary]

1 A BILL to amend the Code of West Virginia, 1931, as amended, by adding a new article,  
 2 designated §16-51A-1, §16-51A-2, §16-51A-3, §16-51A-4, §16-51A-5, §16-51A-6, §16-  
 3 51A-7, and §16-51A-8, relating to the right to try individualized treatments; defining terms;  
 4 defining access to individualized treatments; providing restrictions on outstanding debt  
 5 related to individualized treatments in the event of death; prohibiting sanctions against  
 6 licensed health care providers; prohibiting specified persons from blocking access to  
 7 individualized treatments; prohibiting private right-of-action; providing that the article is not  
 8 to be construed to affect a health benefit plan's obligation to provide coverage for an  
 9 insured's participation in a clinical trial; and setting forth effective date.

*Be it enacted by the Legislature of West Virginia:*

**ARTICLE 51A. RIGHT-TO-TRY INDIVIDUALIZED TREATMENTS.**

**§16-51A-1. Definitions.**

1 The following definitions apply in this article, unless the context requires otherwise:

2 (1) Eligible facility. – Any institution operating under Federal-wide Assurance for the  
 3 Protection of Human Subjects in accordance with 45 C.F.R. § 46 and 42 U.S.C. § 289(a).

4 (2) Eligible patient. – An individual who meets all of the following criteria:

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

6 (b) Has, in consultation with a treating physician, considered all other treatment options  
 7 currently approved by the United States Food and Drug Administration.

8 (c) Has received a recommendation from the treating physician for use of an individualized  
 9 investigational drug, biological product, or device for treatment of the life-threatening or severely  
 10 debilitating illness.

11 (d) Has given informed consent in writing to use of the individualized investigational drug,  
 12 biological product, or device for treatment of the life-threatening or severely debilitating illness or, if  
 13 the individual is a minor or is otherwise incapable of providing informed consent, the parent or  
 14 legal guardian has given informed consent in writing to use of the individualized investigational

15 drug, biological product, or device.

16 (e) Has documentation from the treating physician that the individual meets all of the  
17 criteria for this definition. This documentation shall include an attestation from the treating  
18 physician that the treating physician was consulted in the creation of the written, informed consent  
19 required under this article.

20 (3) Individualized investigational drug, biological product, or device. – A drug, biological  
21 product, or device that is unique and produced exclusively for use for an individual patient, based  
22 on their own genetic profile, including individualized gene therapy antisense oligonucleotides and  
23 individualized neoantigen vaccines.

24 (4) Institution. – As defined in 45 C.F.R. § 46.102(f).

25 (5) Life-threatening or severely debilitating illness. – As those terms are defined in 21  
26 C.F.R. § 312.81.

27 (6) Written, informed consent. – A written document that is signed by an eligible patient; or  
28 if the patient is a minor, by a parent or legal guardian; or if the patient is incapacitated, by a  
29 designated health care agent pursuant to a health care power of attorney, that at a minimum  
30 includes all of the following:

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

33 (b) An explanation that participation is voluntary.

34 (c) An attestation that the eligible patient concurs with the treating physician in believing  
35 that all currently approved treatments are unlikely to prolong the eligible patient's life.

36 (d) Clear identification of the specific individualized investigational drug, biological product,  
37 or device proposed for treatment of the eligible patient's terminal illness.

38 (e) A description of the potentially best and worst outcomes resulting from use of the  
39 individualized investigational drug, biological product, or device to treat the eligible patient's life-  
40 threatening or severely debilitating illness, along with a realistic description of the most likely

41 outcome. The description shall be based on the treating physician's knowledge of the proposed  
42 treatment in conjunction with an awareness of the eligible patient's life-threatening or severely  
43 debilitating illness and shall include a statement acknowledging that new, unanticipated, different,  
44 or worse symptoms might result from, and that death could be hastened by, the proposed  
45 treatment.

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

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

54 (h) A statement that the eligible patient understands that he or she is liable for all expenses  
55 consequent to the use of the individualized investigational drug, biological product, or device and  
56 that this liability extends to the eligible patient's estate, unless a contract between the patient and  
57 the manufacturer of the drug, biological product, or device states otherwise.

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

**§16-51A-2. Authorized access to and use of individualized investigational drugs, biological products, or devices.**

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

4 facility or manufacturer operating within an eligible facility. However, nothing in this article shall be  
5 construed to require a manufacturer of an individualized investigational drug, biological product, or  
6 device to make such individualized investigational drug, biological product, or device available to  
7 an eligible patient.

8 (b) A manufacturer of an individualized investigational drug, biological product, or device  
9 may provide the individualized investigational drug, biological product, or device to an eligible  
10 patient without receiving compensation or may require the eligible patient to pay the costs of, or  
11 the costs associated with, the manufacture of the individualized investigational drug, biological  
12 product, or device.

**§16-51A-3. No liability to heirs for outstanding debt related to use of individualized  
investigational drugs, biological products, or devices.**

1 If an eligible patient dies while being treated with an individualized investigational drug,  
2 biological product, or device, the eligible patient's heirs are not liable for any outstanding debt  
3 related to the treatment, including any costs attributed to lack of insurance coverage for the  
4 treatment.

**§16-51A-4. Sanctions against health care providers prohibited.**

1 (a) A licensing board shall not revoke, fail to renew, suspend, or take any other disciplinary  
2 action against a health care provider licensed under §30-1-1, et seq., based solely on the health  
3 care provider's recommendations to an eligible patient regarding access to or treatment with an  
4 individualized investigational drug, biological product, or device.

5 (b) An entity responsible for Medicare certification shall not take action against a health  
6 care provider's Medicare certification based solely on the health care provider's recommendation  
7 that a patient have access to an individualized investigational drug, biological product, or device.

**§16-51A-5. Prohibited conduct by state officials.**

1 No official, employee, or agent of this state shall block or attempt to block an eligible  
2 patient's access to an individualized investigational drug, biological product, or device.

3 Counseling, advice, or a recommendation consistent with medical standards of care from a  
 4 licensed health care provider, or denial of coverage by the Medicaid program do not constitute a  
 5 violation of this article.

**§16-51A-6. No private right of action against manufacturers of individualized  
 investigational drugs, biological products, or devices.**

1 No private right of action may be brought against a manufacturer of an individualized  
 2 investigational drug, biological product, or device, or against any other person or entity involved in  
 3 the care of an eligible patient using an individualized investigational drug, biological product, or  
 4 device, for any harm caused to the eligible patient resulting from use of the individualized  
 5 investigational drug, biological product, or device as long as the manufacturer or other person or  
 6 entity has made a good-faith effort to comply with the provisions of this article and has exercised  
 7 reasonable care in actions undertaken pursuant to this article.

**§16-51A-7. Insurance coverage of clinical trials.**

1 Nothing in this article shall be construed to affect a health benefit plan's obligation to  
 2 provide coverage for an insured's participation in a clinical trial as set forth in §33-1-1, et seq.

**§16-51A-8. Effective Date.**

1 The provisions of this article are effective on January 1, 2026.

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.