HB 4610

WEST VIRGINIA LEGISLATURE

2026 REGULAR SESSION

ENROLLED

Committee Substitute

for

House Bill 4610

BY DELEGATE HORNBY

[Passed March 14, 2026; in effect 90 days from passage (June 12, 2026)]

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AN ACT to amend and reenact §16-51-3 of the Code of West Virginia, 1931, as amended; and to 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.

[Repealed.]

§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 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.

The Clerk of the House of Delegates and the Clerk of the Senate hereby certify that the foregoing bill is correctly enrolled.

Clerk of the House of Delegates

Clerk of the Senate

FILED
2026 APR -1 P 6:41
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Originated in the House of Delegates.

In effect 90 days from passage.

Speaker of the House of Delegates

President of the Senate

The within is approved this the 1st

Day of April, 2026.

PATRICK MORRISEY

Governor

PRESENTED TO THE GOVERNOR

MAR 25 2025

Time 3:30pm