

WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Introduced

House Bill 2026

2015 Carryover

(BY DELEGATES HOWELL, CANTERBURY, HAMRICK,
AMBLER, ZATEZALO, MCCUSKEY, CADLE, D. EVANS,
ROWAN AND HARTMAN)

[Introduced January 13, 2016; referred to the
Committee on Health and Human Resources then the
Judiciary.]

1 A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article,
 2 designated §16-46-1, §16-46-2, §16-46-3, §16-46-4, §16-46-5, §16-46-6, §16-46-7, and
 3 §16-46-8, all relating to allowing terminally ill patients to have access to investigational
 4 products that have not been approved by the Federal Food and Drug Administration that
 5 other patients have access to when they participate in clinical trials.

Be it enacted by the Legislature of West Virginia:

1 That the Code of West Virginia, 1931, as amended, be amended by adding thereto a
 2 new article, designated §16-46-1, §16-46-2, §16-46-3, §16-46-4, §16-46-5, §16-46-6, §16-46-7,
 3 and §16-46-8, all to read as follows:

ARTICLE 46. RIGHT TO TRY ACT.

§16-46-1. Short title.

1 This article shall be known and may be cited as the "Right to Try Act."

§16-46-2. Legislative declaration.

1 (a) The Legislature finds and declares that:

2 (1) The process of approval for investigational drugs, biological products and devices in
 3 the United States protects future patients from premature, ineffective and unsafe medications
 4 and treatments over the long run, but the process often takes many years;

5 (2) Patients who have a terminal illness do not have the luxury of waiting until an
 6 investigational drug, biological product or device receives final approval from the United States
 7 Food and Drug Administration;

8 (3) Patients who have a terminal illness have a fundamental right to attempt to pursue
 9 the preservation of their own lives by accessing available investigational drugs, biological
 10 products and devices;

11 (4) The use of available investigational drugs, biological products and devices is a

12 decision that should be made by the patient with a terminal illness in consultation with the
13 patient's health care provider and the patient's health care team, if applicable; and

14 (5) The decision to use an investigational drug, biological product or device should be
15 made with full awareness of the potential risks, benefits and consequences to the patient and
16 the patient's family.

17 (b) It is the intent of the Legislature to allow for terminally ill patients to use potentially
18 life-saving investigational drugs, biological products and devices.

§16-46-3. 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;

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

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

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

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

15 (F) Documentation from his or her physician that he or she meets the requirements of
16 this subdivision (1).

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

18 licensed or certified pursuant to article five-b, chapter sixteen, section one [§16-5B-1] of this
19 code.

20 (3) "Investigational drug, biological product or device" means a drug, biological product or
21 device that has successfully completed phase one of a clinical trial but has not yet been
22 approved for general use by the United States Food and Drug Administration and remains under
23 investigation in a United States Food and Drug Administration-approved clinical trial.

24 (4) "Terminal illness" means a disease that, without life-sustaining procedures, will soon
25 result in death or a state of permanent unconsciousness from which recovery is unlikely.

26 (5) "Written, informed consent" means a written document signed by the patient and
27 attested to by the patient's physician and a witness that, at a minimum:

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

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

33 (C) Clearly identifies the specific proposed investigational drug, biological product or
34 device that the patient is seeking to use;

35 (D) Describes the potentially best and worst outcomes of using the investigational drug,
36 biological product or device with a realistic description of the most likely outcome, including the
37 possibility that new, unanticipated, different or worse symptoms might result, and that death
38 could be hastened by the proposed treatment, based on the physician's knowledge of the
39 proposed treatment in conjunction with an awareness of the patient's condition;

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

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

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

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

**§16-46-4. Drug manufacturers - availability of investigational drugs, biological products
or devices - costs - insurance coverage.**

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

5 (b) A manufacturer may:

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

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

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

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

14 (e) An insurer may deny coverage to an eligible patient from the time the eligible patient
15 begins use of the investigational drug, biologic product or device through a period not to exceed

16 six months from the time the investigational drug, biologic product or device is no longer used by
17 the eligible patient; except that coverage may not be denied for a preexisting condition and for
18 coverage for benefits which commenced prior to the time the eligible patient begins use of such
19 drug, biologic product or device.

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

§16-46-5. Action against health care provider's license or medicare certification prohibited.

1 Notwithstanding any other law, a licensing board may not revoke, fail to renew, suspend
2 or take any action against a health care provider's license issued pursuant to chapter thirty of
3 this code, based solely on the health care provider's recommendations to an eligible patient
4 regarding access to or treatment with an investigational drug, biological product or device, as
5 long as the recommendations are consistent with medical standards of care. Action against a
6 health care provider's medicare certification based solely on the health care provider's
7 recommendation that a patient have access to an investigational drug, biological product or
8 device is prohibited.

§16-46-6. Access to investigational drugs, biological products and devices.

1 An official, employee or agent of this state shall not block or attempt to block an eligible
2 patient's access to an investigational drug, biological product or device. Counseling, advice or
3 a recommendation consistent with medical standards of care from a licensed health care
4 provider is not a violation of this section.

§16-46-7. No cause of action created.

1 This article does not create a private cause of action against a manufacturer of an
2 investigational drug, biological product or device or against any other person or entity involved in

3 the care of an eligible patient using the investigational drug, biological product or device, for any
4 harm done to the eligible patient resulting from the investigational drug, biological product or
5 device, so long as the manufacturer or other person or entity is complying in good faith with the
6 terms of this article, unless there was a failure to exercise reasonable care.

§16-46-8. Affect on health care coverage.

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

NOTE: The purpose of this bill is to allow terminally ill patients to have access to investigational products that have not been approved by the federal food and drug administration that other patients have access to when they participate in clinical trials.

This article is new; therefore, it has been completely underscored.