

WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Enrolled

Senate Bill 416

BY SENATORS TAKUBO, TRUMP, BLAIR AND KESSLER

[Passed March 10, 2016; in effect 90 days from passage]

1 AN ACT to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article,
2 designated §16-51-1, §16-51-2, §16-51-3, §16-51-4, §16-51-5, §16-51-6, §16-51-7 and
3 §16-51-8, 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; establishing a short
6 title; setting out legislative findings; defining terms; allowing drug manufacturers to provide
7 investigative products; setting forth insurance requirements; and prohibiting action.

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 new
2 article, designated §16-51-1, §16-51-2, §16-51-3, §16-51-4, §16-51-5, §16-51-6, §16-51-7 and
3 §16-51-8, all to read as follows:

ARTICLE 51. RIGHT TO TRY ACT.

§16-51-1. Short title.

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

§16-51-2. Legislative findings.

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 and
4 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 the
9 preservation of their own lives by accessing available investigational drugs, biological products
10 and devices;

11 (4) The use of available investigational drugs, biological products and devices is a decision
12 that should be made by the patient with a terminal illness in consultation with the patient's health
13 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 the
16 patient's family.

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

§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;

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 this
16 subdivision.

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 of this code.

19 (3) “Investigational drug, biological product or device” means a drug, biological product or
20 device that has successfully completed phase one of a clinical trial but has not yet been approved
21 for general use by the United States Food and Drug Administration.

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

24 (5) “Written, informed consent” means a written document signed by the patient and
25 attested to by the patient’s physician and a witness that, at a minimum:

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

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

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

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

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

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

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

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

**§16-51-4. 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 thirty-
11 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 and estate are not liable for any outstanding debt related to the
22 treatment or lack of insurance due to the treatment.

§16-51-5. 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 this
3 code based solely on the health care provider's recommendations to an eligible patient regarding
4 access to or treatment with an investigational drug, biological product or device as long as the
5 recommendations are consistent with medical standards of care. Action against a health care
6 provider's Medicare certification based solely on the health care provider's recommendation that
7 a patient have access to an investigational drug, biological product or device is prohibited.

§16-51-6. 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 a
3 recommendation consistent with medical standards of care from a licensed health care provider
4 is not a violation of this section.

§16-51-7. 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, against a health care provider as defined in
3 section two, article seven-b, chapter fifty-five of this Code, or against any other person or entity
4 involved in the care of an eligible patient using the investigational drug, biological product or
5 device, for any harm done to the eligible patient resulting from the investigational drug, biological

6 product or device, so long as the manufacturer, health care provider, or other person or entity is
7 complying in good faith with the terms of this article.

§16-51-8. Effect on health care coverage.

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

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

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Chairman, Senate Committee

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Chairman, House Committee

Originated in the Senate.

In effect 90 days from passage.

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Clerk of the Senate

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Clerk of the House of Delegates

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President of the Senate

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Speaker of the House of Delegates

The within this the.....
Day of, 2016.

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Governor