

SENATE BILL NO. 142

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A BILL FOR AN ACT ENTITLED: "AN ACT AUTHORIZING ACCESS TO AND THE USE OF EXPERIMENTAL
 TREATMENTS FOR A TERMINAL ILLNESS; ESTABLISHING CONDITIONS FOR THE USE OF
 EXPERIMENTAL TREATMENTS; PROHIBITING SANCTIONS OF HEALTH CARE PROVIDERS; CLARIFYING
 THE DUTIES OF HEALTH INSURERS REGARDING EXPERIMENTAL TREATMENTS; PROHIBITING CERTAIN
 ACTIONS BY STATE OFFICIALS; ~~AND PROVIDING IMMUNITY;~~ AND PROVIDING AN IMMEDIATE EFFECTIVE
 DATE."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Short title.** [Sections 1 through 10] may be cited as the "Right to Try Act".

NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through 10], the following definitions
 apply:

- (1) "Eligible patient" means an individual who meets the requirements of [section 4];
- (2) "HEALTH CARE FACILITY" HAS THE MEANING PROVIDED IN 50-5-101.
- ~~(2)~~(3) "Health care provider" means any of the following individuals licensed pursuant to Title 37:
 - (a) a physician;
 - (b) an advanced practice registered nurse authorized by the board of nursing to prescribe medicine; and

1 (c) a physician assistant whose duties and delegation agreement allows the physician assistant to
2 undertake the activities allowed under [sections 1 through 10].

3 ~~(3)~~(4) "Investigational drug, biological product, or device" means a drug, biological product, or device
4 that:

5 (a) has successfully completed phase 1 of a clinical trial but has not yet been approved for general use
6 by the United States food and drug administration; and

7 (b) remains under investigation in a United States food and drug administration-approved clinical trial.

8 ~~(4)~~(5) "Terminal illness" means a progressive disease or medical or surgical condition that:

9 (a) entails significant functional impairment;

10 (b) is not considered by a treating health care provider to be reversible even with administration of a
11 treatment currently approved by the United States food and drug administration; and

12 (c) without life-sustaining procedures, will result in death.

13 ~~(5)~~(6) "Written informed consent" means a written document that meets the requirements of [section 5].

14
15 **NEW SECTION. Section 3. Availability of experimental drugs.** (1) A manufacturer of an
16 investigational drug, biological product, or device may make the drug, product, or device available to an eligible
17 patient who has requested the drug, product, or device pursuant to [sections 1 through 10].

18 (2) The manufacturer may:

19 (a) provide an investigational drug, biological product, or device to an eligible patient without receiving
20 compensation; or

21 (b) require an eligible patient to pay the costs of or the costs associated with the manufacture of the
22 investigational drug, biological product, or device.

23 (3) A manufacturer is not required to make an investigational drug, biological product, or device available
24 to an eligible patient.

25
26 **NEW SECTION. Section 4. Eligible patient -- requirements.** A patient is eligible for treatment with
27 an investigational drug, biological product, or device if the patient has:

28 (1) a terminal illness that is attested to by the patient's treating health care provider;

29 (2) considered all other treatment options currently approved by the United States food and drug
30 administration;

1 (3) received a recommendation from the patient's treating health care provider for an investigational drug,
2 biological product, or device;

3 (4) given written informed consent for the use of the investigational drug, biological product, or device;
4 and

5 (5) documentation from the treating health care provider that the patient meets the requirements of this
6 section.

7
8 **NEW SECTION. Section 5. Written informed consent required.** (1) A patient or a patient's legal
9 guardian must provide written informed consent for treatment with an investigational drug, biological product, or
10 device.

11 (2) At a minimum, the written informed consent must include:

12 (a) an explanation of the currently approved products and treatments for the disease or condition from
13 which the patient suffers;

14 (b) an attestation that the patient concurs with the treating health care provider in believing that all
15 currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

16 (c) clear identification of the specific investigational drug, biological product, or device that the patient
17 is seeking to use;

18 (d) a description of the potentially best and worst outcomes of using the investigational drug, biological
19 product, or device and a realistic description of the most likely outcome;

20 (e) a statement that the patient's health plan or third-party administrator and provider are not obligated
21 to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device
22 unless they are specifically required to do so by law or contract;

23 (f) a statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative
24 treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if
25 the treatment ends and the patient meets hospice eligibility requirements; and

26 (g) a statement that the patient understands that the patient is liable for all expenses related to the use
27 of the investigational drug, biological product, or device and that the liability for expenses extends to the patient's
28 estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device
29 states otherwise.

30 (3) The description of potential outcomes required under subsection (2)(d) must:

1 (a) include the possibility that new, unanticipated, different, or worse symptoms might result and that the
2 proposed treatment could hasten death; and

3 (b) be based on the treating health care provider's knowledge of the proposed treatment in conjunction
4 with an awareness of the patient's condition.

5 (4) The written informed consent must be:

6 (a) signed by:

7 (i) the patient;

8 (ii) a parent or legal guardian, if the patient is a minor; or

9 (iii) a legal guardian, if a guardian has been appointed pursuant to Title 72, chapter 5; and

10 (b) attested to by the patient's treating health care provider and a witness.

11
12 **NEW SECTION. Section 6. Effect on insurance coverage and health care services.** (1) [Sections
13 1 through 10] do not:

14 (a) expand the coverage required of an insurer under Title 33 or of the state or a local government under
15 Title ~~48~~ 2 or Title 53;

16 (b) affect the requirements for insurance coverage of routine patient costs for patients involved in
17 approved cancer clinical trials pursuant to 2-18-704, 33-22-101, 33-22-153, 33-31-111, 33-35-306, 53-4-1005,
18 or 53-6-101;

19 (c) require a health plan, third-party administrator, or governmental agency to pay costs associated with
20 the use, care, or treatment of an eligible patient with an investigational drug, biological product, or device; or

21 (d) require a ~~hospital or health care facility licensed under Title 50, chapter 5~~, to provide new or additional
22 services.

23 (2) A health plan, third-party administrator, or governmental agency may provide coverage for the cost
24 of an investigational drug, biological product, or device or the cost of services related to the use of an
25 investigational drug, biological product, or device under [sections 1 through 10].

26 (3) A ~~hospital or health care facility~~ may approve the use of an investigational drug, biological product,
27 or device in the ~~hospital or health care facility~~.

28
29 **NEW SECTION. Section 7. Heirs not liable for payments.** If an eligible patient dies while being treated
30 with an investigational drug, biological product, or device, the patient's heirs are not liable for any outstanding debt

1 related to the treatment or to a lack of insurance as a result of the treatment.

2

3 **NEW SECTION. Section 8. Disciplinary action prohibited.** (1) A licensing board may not revoke, fail
4 to renew, suspend, or take any action against a license issued under Title 37 to a health care provider based
5 solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with
6 an investigational drug, biological product, or device.

7 (2) The department of public health and human services may not take action against a health care
8 provider's medicare certification based solely on the health care provider's recommendation that a patient have
9 access to an investigational drug, biological product, or device.

10

11 **NEW SECTION. Section 9. State action prohibited.** (1) An official, employee, or agent of the state
12 of Montana may not block or attempt to block an eligible patient's access to an investigational drug, biological
13 product, or device.

14 (2) Counseling, advice, or a recommendation consistent with medical standards of care from a licensed
15 health care provider is not a violation of this section.

16

17 **NEW SECTION. Section 10. Immunity from suit.** A manufacturer of an investigational drug, biological
18 product, or device, a pharmacist, A HEALTH CARE FACILITY, A HEALTH CARE PROVIDER, or a person or entity involved
19 in the care of an eligible patient using an investigational drug, biological product, or device is immune from suit
20 for any harm done to the eligible patient resulting from the investigational drug, biological product, or device if the
21 manufacturer, PHARMACIST, HEALTH CARE FACILITY, HEALTH CARE PROVIDER, or other person or entity is complying
22 in good faith with the terms of this act and has exercised reasonable care.

23

24 **NEW SECTION. Section 11. Codification instruction.** [Sections 1 through 10] are intended to be
25 codified as an integral part of Title 50, chapter 9, and the provisions of Title 50, chapter 9, apply to [sections 1
26 through 10].

27

28 **NEW SECTION. Section 12. Severability.** If a part of [this act] is invalid, all valid parts that are
29 severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications,
30 the part remains in effect in all valid applications that are severable from the invalid applications.

