
A BILL FOR AN ACT

RELATING TO ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS.

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

1 SECTION 1. The legislature finds that the process of
2 approval for investigational drugs, biological products, and
3 devices in the United States protects future patients from
4 premature, ineffective, and unsafe medications and treatments
5 over the long run, but the process often takes many years.
6 Patients who have a terminal illness do not have the luxury of
7 waiting until an investigational drug, biological product, or
8 device receives final approval from the United States Food and
9 Drug Administration.

10 According to the National Conference of the State
11 Legislatures, as of the end of 2015, twenty-five states have
12 enacted "right-to-try" legislation that makes available
13 experimental drugs without Food and Drug Administration approval
14 to terminally ill patients with no other medication or treatment
15 options.



1 The purpose of this Act is to allow for terminally ill
2 patients to use potentially life-saving investigational drugs,
3 and biological products.

4 SECTION 2. Chapter 321, Hawaii Revised Statutes, is
5 amended by adding a new section to be appropriately designated
6 and to read as follows:

7 "§321- Access to investigational drugs, biological
8 products, or devices for terminally ill patients. (a) For the
9 purposes of this section:

10 "Eligible patient" means a person who has:

11 (1) A terminal illness, attested to by the patient's
12 treating physician;

13 (2) Considered all other treatment options currently
14 approved by the United States Food and Drug
15 Administration;

16 (3) Been unable to participate in a clinical trial for the
17 terminal illness within one hundred miles of the
18 patient's home address for the terminal illness, or
19 not been accepted to the clinical trial within one
20 week of completion of the clinical trial application
21 process;



1 (4) Received a recommendation from the patient's physician
2 for an investigational drug, biological product;

3 (5) Given written, informed consent for the use of the
4 investigational drug or biological product or, if the
5 patient is a minor or lacks the mental capacity to
6 provide informed consent, a parent or legal guardian
7 has given written, informed consent on the patient's
8 behalf; and

9 (6) Documentation from the patient's physician that the
10 patient meets the requirements of this definition.

11 "Eligible patient" does not include a person being treated as an
12 inpatient in an institution with an organized medical staff,
13 regulated under section 321-11(10), or a health care facility
14 under chapter 323F.

15 "Investigational drug, biological product, or device" means
16 a drug, biological product, or device that has successfully
17 completed phase one of a clinical trial but has not yet been
18 approved for general use by the United States Food and Drug
19 Administration and remains under investigation in a United
20 States Food and Drug Administration-approved clinical trial.



1 "Terminal illness" means a disease that, without life-
2 sustaining procedures, will soon result in death or a state of
3 permanent unconsciousness from which recovery is unlikely.

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

7 (1) Explains the currently approved products and
8 treatments for the disease or condition from which the
9 patient suffers;

10 (2) Attests to the fact that the patient concurs with the
11 patient's physician in believing that all currently
12 approved and conventionally recognized treatments are
13 unlikely to prolong the patient's life;

14 (3) Clearly identifies the specific proposed
15 investigational drug or biological product that the
16 patient is seeking to use;

17 (4) Describes the potentially best and worst outcomes of
18 using the investigational drug or biological product
19 with a realistic description of the most likely
20 outcome, including the possibility that new,
21 unanticipated, different, or worse symptoms might



1 result, and that death could be hastened by the
2 proposed treatment, based on the physician's knowledge
3 of the proposed treatment in conjunction with an
4 awareness of the patient's condition;

5 (5) Makes clear that the patient's health insurer and
6 provider are not obligated to pay for any care or
7 treatments consequent to the use of the
8 investigational drug or biological product;

9 (6) Makes clear that the patient's eligibility for hospice
10 care may be withdrawn by the hospice care provider if
11 the patient begins curative treatment and care may be
12 reinstated if the curative treatment ends and the
13 patient meets hospice eligibility requirements;

14 (7) Makes clear that in-home health care may be denied if
15 treatment begins; and

16 (8) States that the patient understands that the patient
17 is liable for all expenses consequent to the use of
18 the investigational drug or biological product, and
19 that this liability extends to the patient's estate,
20 unless a contract between the patient and the



1 manufacturer of the drug or biological product states
2 otherwise.

3 (b) Notwithstanding section 328-17, beginning January 1,
4 2023, a manufacturer of an investigational drug, biological
5 product, or device may make available the manufacturer's
6 investigational drug, biological product, or device to eligible
7 patients pursuant to this section. This section does not
8 require that a manufacturer make available an investigational
9 drug or biological product to an eligible patient. A
10 manufacturer may:

11 (1) Provide an investigational drug or biological product
12 to an eligible patient without receiving compensation;
13 or

14 (2) Require an eligible patient to pay the costs of, or
15 the costs associated with, the manufacture of the
16 investigational drug or biological product.

17 (c) A health insurance carrier may, but is not required
18 to, provide coverage for the cost of an investigational drug or
19 biological product.

20 (d) An insurer may deny coverage to an eligible patient
21 from the time the eligible patient begins use of the



1 investigational drug or biological product through a period not
2 to exceed six months from the time the investigational drug or
3 biological product may not be denied for a preexisting condition
4 and for coverage for benefits that commence prior to the time
5 the eligible patient begins use of such investigational drug or
6 biological product.

7 (e) If a patient dies while being treated by an
8 investigational drug or biological product, the patient's heirs
9 shall not be liable for any outstanding debt related to the
10 treatment or lack of insurance due to the treatment.

11 (f) Notwithstanding any law to the contrary, a licensing
12 board may not revoke, fail to renew, suspend, or take any action
13 against a health care provider's license based on the health
14 care provider's recommendations to an eligible patient regarding
15 access to or treatment with an investigational drug or
16 biological product that is being developed to treat the type of
17 terminal illness that afflicts the patient. Action against a
18 health care provider's medicare certification based on the
19 health care provider's recommendation that a patient have access
20 to an investigational drug or biological product that is being



1 developed to treat the type of terminal illness that afflicts
2 the patient is prohibited.

3 (g) An official, employee, or agent of the State shall not
4 block or attempt to block an eligible patient's access to an
5 investigational drug or biological product. Counseling, advice,
6 or a recommendation consistent with medical standards of care
7 from a licensed health care provider is not a violation of this
8 section.

9 (h) This section does not create a private cause of action
10 against a manufacturer of an investigational drug or biological
11 product or against another person or entity involved in the care
12 of an eligible patient using the investigational drug or
13 biological product, for any harm done to the eligible patient
14 resulting from the investigational drug or biological product,
15 so long as the manufacturer or other person or entity is
16 complying in good faith with the terms of this section, unless
17 there was a failure to exercise reasonable care."

18 SECTION 3. New statutory material is underscored.

19 SECTION 4. If any provision of this Act, or the
20 application thereof to any person or circumstance, is held
21 invalid, the invalidity does not affect other provisions or

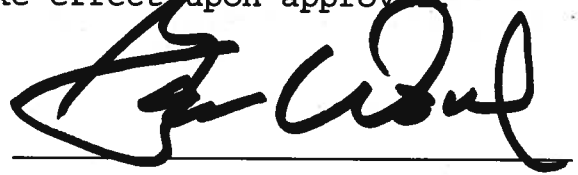


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1 applications of the Act that can be given effect without the
2 invalid provision or application, and to this end the provisions
3 of this Act are severable.

4 SECTION 5. This Act shall take effect upon approval
5

INTRODUCED BY:



JAN 21 2022



H.B. NO. 1918

Report Title:

Right to Try.

Description:

Codifies a terminally ill patient's right to try experimental treatment options.

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