

JAN 17 2024

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# 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 and biological products in  
3 the United States protects future patients from premature,  
4 ineffective, and unsafe medications and treatments over the long  
5 run, but the process often takes many years. Patients who have  
6 a terminal illness can be severely restricted in care options  
7 until an investigational drug or biological product receives  
8 final approval from the United States Food and Drug  
9 Administration.

10           The legislature further finds that because patients who  
11 have a terminal illness may often not have the time to wait for  
12 a potentially lifesaving investigational drug or biological  
13 product to gain final approval from the United States Food and  
14 Drug Administration, the federal government and forty-one states  
15 have enacted "right-to-try" legislation that makes available  
16 experimental drugs without Food and Drug Administration approval



1 to terminally ill patients with no other medication or treatment  
2 options.

3 The purpose of this Act is to grant patients with terminal  
4 illnesses access to potentially lifesaving investigational drugs  
5 and biological products that have not received final approval  
6 from the United States Food and Drug Administration.

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

10 "§321- Access to investigational drugs and biological  
11 products for terminally ill patients. (a) Notwithstanding  
12 section 328-17, beginning January 1, 2025, a manufacturer of an  
13 investigational drug or biological product may make available  
14 the manufacturer's investigational drug or biological product to  
15 eligible patients pursuant to this section. A manufacturer may:

16 (1) Provide an investigational drug or biological product  
17 to an eligible patient without receiving compensation;  
18 or

19 (2) Require an eligible patient to pay the costs of, or  
20 the costs associated with, the manufacture of the  
21 investigational drug or biological product.



1        (b) A health insurer may provide coverage for the cost of  
2 an investigational drug or biological product.

3        (c) A health insurer may deny coverage to an eligible  
4 patient from the time the eligible patient begins use of the  
5 investigational drug or biological product through a period not  
6 to exceed six months from the time the investigational drug or  
7 biological product is no longer used by the eligible patient;  
8 provided that a health insurer shall not deny coverage for:

9        (1) A preexisting condition; or

10       (2) Benefits that commence before the time the eligible  
11 patient begins use of the investigational drug or  
12 biological product.

13       (d) If a patient dies while being treated with an  
14 investigational drug or biological product, the patient's heirs  
15 shall not be liable for any outstanding debt related to the  
16 treatment or lack of insurance due to the treatment.

17       (e) Notwithstanding any law to the contrary, a licensing  
18 board shall not revoke, fail to renew, suspend, or take any  
19 action against a health care provider's license based on the  
20 health care provider's recommendation to an eligible patient  
21 regarding access to or treatment with an investigational drug or



1 biological product that is being developed to treat the type of  
2 terminal illness that afflicts the patient, any physical or  
3 psychological symptoms of the patient's terminal illness, or for  
4 palliative care. Action against a health care provider's  
5 medicare certification based on the health care provider's  
6 recommendation that a patient have access to an investigational  
7 drug or biological product that is being developed to treat the  
8 type of terminal illness that afflicts the patient, any physical  
9 or psychological symptoms of the patient's terminal illness, or  
10 for palliative care shall be prohibited.

11 (f) An official, employee, or agent of the State shall not  
12 block or attempt to block an eligible patient's access to an  
13 investigational drug or biological product. Counseling, advice,  
14 or a recommendation consistent with medical standards of care  
15 from a licensed health care provider shall not constitute a  
16 violation of this section.

17 (g) This section does not create a private cause of action  
18 against a manufacturer of an investigational drug or biological  
19 product, or against another person or entity involved in the  
20 care of an eligible patient using the investigational drug or  
21 biological product, for any harm done to the eligible patient



1 resulting from the investigational drug or biological product;  
2 provided that the manufacturer or other person or entity  
3 complies in good faith with the terms of this section; provided  
4 further that there was no failure to exercise reasonable care.

5 (h) For the purposes of this section:

6 "Eligible patient" means a person who has:

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

9 (2) Considered all other treatment options currently  
10 approved by the United States Food and Drug  
11 Administration;

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

18 (4) Received a recommendation from the patient's treating  
19 physician for an investigational drug or biological  
20 product to treat the patient's terminal illness,



1           physical or psychological symptoms of the patient's  
2           terminal illness, or for palliative care;

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 treating physician  
10           that the patient meets the requirements of paragraphs  
11           (1) through (5).

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

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



1       "Terminal illness" means a disease that, without life-  
2 sustaining procedures, will 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 eligible patient and attested to by the patient's  
6 treating physician and a witness that, at a minimum:

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

10       (2) Attests to the fact that the patient concurs with the  
11 patient's treating physician in believing that all  
12 existing approved and conventionally recognized  
13 treatments are 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 treating physician's  
3           knowledge of the proposed treatment in conjunction  
4           with an awareness of the patient's condition;

5           (5) Makes clear that the patient's health insurer and  
6           health care provider are not obligated to pay for any  
7           care or 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 investigational drug or biological  
2           product states otherwise."

3           SECTION 3. New statutory material is underscored.

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

5

INTRODUCED BY: 



# S.B. NO. 2023

**Report Title:**

Right-to-Try Act; Terminally Ill Patients; Investigational  
Drugs; Biological Products

**Description:**

Beginning on January 1, 2025, permits manufacturers of  
investigational drugs or biological products to make these drugs  
and products available to terminally ill patients under certain  
conditions.

*The summary description of legislation appearing on this page is for informational purposes only and is  
not legislation or evidence of legislative intent.*

