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# A BILL FOR AN ACT

RELATING TO TERMINAL ILLNESSES.

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

1           SECTION 1. The legislature finds that patients who are  
2 terminally ill deserve timely access to medical treatments or  
3 palliative care, even if the medications are pending approval by  
4 the United States Food and Drug Administration. While the Food  
5 and Drug Administration's approval process is intended to  
6 protect patients from premature, ineffective, or unsafe  
7 medications and products, gaining final approval for a  
8 medication or product can take many years. Terminally ill  
9 patients may have their care options severely restricted until  
10 an investigational drug or biological product is approved for  
11 general use. Given the patients' diagnoses and the state of  
12 their health, they may not have time to wait.

13           The legislature recognizes that, to help terminally ill  
14 patients obtain timely access to medical treatments, the federal  
15 government and forty-one states have enacted "right-to-try"  
16 legislation that makes available to these patients drugs that  
17 are pending approval by the Food and Drug Administration.





1           clinical trial within one week of completing the  
2           clinical trial application process;

3           (4) Has a recommendation from the person's treating health  
4           care provider to try an investigational drug or  
5           biological product to treat the person's terminal  
6           illness, ease physical or psychological symptoms of  
7           the terminal illness, or for purposes of palliative  
8           care;

9           (5) Provides informed consent for the use of the  
10          investigational drug or biological product; provided  
11          that if the person is a minor or lacks the mental  
12          capacity to provide informed consent, the person's  
13          parent or legal guardian shall provide informed  
14          consent on the person's behalf; and

15          (6) Provides documentation from the person's treating  
16          health care provider that the person meets the  
17          requirements of paragraphs (1) through (5).

18          "Eligible patient" does not include a person being treated  
19          on an inpatient basis at an institution with an organized  
20          medical staff, at a facility regulated pursuant to section



1 321-11(10), or at a health care facility regulated pursuant to  
2 chapter 323F.

3 "Health care provider" has the same meaning as "licensed  
4 health care provider" as defined in section 321-31.5.

5 "Informed consent" means a written document signed by the  
6 eligible patient, or the eligible patient's legal  
7 representative, and attested to by the patient's treating health  
8 care provider, that:

9 (1) Lists the existing medications and biological products  
10 that are approved by the United States Food and Drug  
11 Administration to treat the patient's terminal  
12 illness;

13 (2) Attests to the fact that the treating health care  
14 provider finds, and the patient agrees, that no  
15 treatment listed in paragraph (1) is likely to prolong  
16 the patient's life;

17 (3) Identifies the specific proposed investigational drug  
18 or biological product to which the patient seeks  
19 access;

20 (4) Describes, based on the treating health care  
21 provider's knowledge of the proposed treatment and the



1 patient's condition, the possible best, worst, and  
2 most likely outcomes if the patient uses the  
3 investigational drug or biological product, including  
4 the possibility that the treatment may cause new,  
5 unanticipated, different, or exacerbated symptoms or  
6 that the treatment may hasten the patient's death; and

7 (5) States expressly that:

8 (A) The patient's health insurer and health care  
9 provider are not obligated to pay for any care or  
10 treatment needed as a consequence of the  
11 investigational drug or biological product;

12 (B) The patient's eligibility for hospice care may be  
13 withdrawn by a hospice care provider if the  
14 patient begins a potentially curative treatment;  
15 provided that hospice care may be reinstated if,  
16 after the potentially curative treatment ends,  
17 the patient meets hospice eligibility  
18 requirements;

19 (C) In-home health care services may be denied if the  
20 patient begins treatment with an investigative  
21 drug or biological product; and



1 (D) The patient understands that the patient is  
2 responsible for all expenses resulting from the  
3 use of the investigational drug or biological  
4 product, unless financial liability is otherwise  
5 established in a contract between the patient and  
6 the manufacturer of the investigational drug or  
7 biological product.

8 "Investigational drug or biological product" means a drug  
9 or biological product that has successfully completed phase one  
10 of a clinical trial approved by the United States Food and Drug  
11 Administration but has not yet been cleared for general use.

12 "Terminal illness" means an illness that, without  
13 life-sustaining procedures, will result in the person's death or  
14 a state of permanent unconsciousness from which recovery is  
15 unlikely.

16 § -2 **Terminally ill patients; access to investigational**  
17 **drugs or biological products.** (a) Notwithstanding section  
18 328-17, the manufacturer of an investigational drug or  
19 biological product may make the drug or product available to an  
20 eligible patient; provided that the manufacturer may:



1 (1) Offer the investigational drug or biological product  
2 at no cost to the eligible patient; or

3 (2) Charge to the eligible patient, or the patient's  
4 health insurer, the costs of manufacturing the  
5 investigational drug or biological product.

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

8 (c) A health insurer may deny health care coverage to an  
9 eligible patient from the time the eligible patient begins using  
10 an investigational drug or biological product until a maximum of  
11 six months after the eligible patient ceases use of the  
12 investigational drug or biological product; provided that a  
13 health insurer shall not deny coverage for:

14 (1) A preexisting condition; or

15 (2) Benefits that commenced before the eligible patient  
16 began using the investigational drug or biological  
17 product.

18 (d) If a patient dies while being treated with an  
19 investigational drug or biological product, the patient's heirs  
20 and estate shall not be liable for any outstanding debt related



1 to the treatment, or for any balance not covered by health  
2 insurance.

3 (e) Notwithstanding any law to the contrary, no licensing  
4 board in the State shall revoke, fail to renew, suspend, or take  
5 any action against a health care provider's professional license  
6 or medicare certification based on the health care provider's  
7 recommendation to an eligible patient regarding access to or  
8 treatment with an investigational drug or biological product  
9 that is being developed:

10 (1) To treat the type of terminal illness that afflicts  
11 the patient;

12 (2) To ease the physical or psychological symptoms of the  
13 terminal illness; or

14 (3) For purposes of palliative care.

15 (f) No official, employee, or agent of the State shall  
16 block or attempt to block an eligible patient's access to an  
17 investigational drug or biological product. Counseling, advice,  
18 or recommendations from a licensed health care provider that are  
19 consistent with medical standards of care shall not constitute a  
20 violation of this section.



1 (g) This section does not create a private cause of action  
2 against the manufacturer of an investigational drug or  
3 biological product, or against another person or entity involved  
4 in the care of an eligible patient who is using an investigative  
5 drug or biological product, for any harm to the eligible patient  
6 that results from the use of the investigational drug or  
7 biological product if the manufacturer, person, or entity  
8 complied in good faith with the terms of this section and  
9 exercised reasonable care."

10 SECTION 3. This Act shall take effect on December 31,  
11 2050.



**Report Title:**

Terminal Illness; Investigative Drug or Biological Product;  
Access to Care; Right-to-Try

**Description:**

Authorizes manufacturers of investigational drugs or biological products that are pending approval by the United States Food and Drug Administration to make the drugs or products available to terminally ill patients under certain conditions. Effective 12/31/2050. (SD1)

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