

JAN 19 2018

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 The legislature also finds that patients who have a
11 terminal illness have a fundamental right to pursue the
12 preservation of their own lives by accessing available
13 investigational drugs, biological products, and devices. The
14 use of available investigational drugs, biological products, and
15 devices is a decision that should be made by the patient with a
16 terminal illness in consultation with the patient's health care
17 provider and the patient's health care team, if applicable. The



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1 decision to use an investigational drug, biological product, or
2 device should be made with full awareness of the potential
3 risks, benefits, and consequences to the patient and the
4 patient's family.

5 The purpose of this Act is to allow for terminally ill
6 patients to use potentially life-saving investigational drugs,
7 biological products, and devices.

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

11 "§321- Access to investigational drugs, biological
12 products, or devices for terminally ill patients. (a)
13 Beginning January 1, 2019, a manufacturer of an investigational
14 drug, biological product, or device may make available the
15 manufacturer's investigational drug, biological product, or
16 device to eligible patients pursuant to this section. This
17 section does not require that a manufacturer make available an
18 investigational drug, biological product, or device to an
19 eligible patient. A manufacturer may:



1 (1) Provide an investigational drug, biological product,
2 or device to an eligible patient without receiving
3 compensation; or

4 (2) Require an eligible patient to pay the costs of, or
5 the costs associated with, the manufacture of the
6 investigational drug, biological product, or device.

7 (b) A health insurance carrier may, but is not required
8 to, provide coverage for the cost of an investigational drug,
9 biological product, or device.

10 (c) An insurer may deny coverage to an eligible patient
11 from the time the eligible patient begins use of the
12 investigational drug, biological product, or device through a
13 period not to exceed six months from the time the
14 investigational drug, biological product, or device is no longer
15 used by the eligible patient; provided that coverage may not be
16 denied for a preexisting condition and for coverage for benefits
17 that commence prior to the time the eligible patient begins use
18 of such drug, biological product, or device.

19 (d) If a patient dies while being treated by an
20 investigational drug, biological product, or device, the



1 patient's heirs are not liable for any outstanding debt related
2 to the treatment or lack of insurance due to the treatment.

3 (e) Notwithstanding any law to the contrary, a licensing
4 board may not revoke, fail to renew, or suspend a health care
5 provider's license or take any action against a health care
6 provider based solely on the health care provider's
7 recommendations to an eligible patient regarding access to or
8 treatment with an investigational drug, biological product, or
9 device, as long as the recommendations are consistent with
10 medical standards of care. Action against a health care
11 provider's medicare certification based solely on the health
12 care provider's recommendation that a patient have access to an
13 investigational drug, biological product, or device is
14 prohibited.

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



1 (g) This section does not create a private cause of action
2 against a manufacturer of an investigational drug, biological
3 product, or device or against another person or entity involved
4 in the care of an eligible patient using the investigational
5 drug, biological product, or device, for any harm done to the
6 eligible patient resulting from the investigational drug,
7 biological product, or device, so long as the manufacturer or
8 other person or entity is complying in good faith with the terms
9 of this section, unless there was a failure to exercise
10 reasonable care.

11 (h) For the purposes of this section:

12 "Eligible patient" means a person who has:

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

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

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



1 week of completion of the clinical trial application
2 process;

3 (4) Received a recommendation from the patient's physician
4 for an investigational drug, biological product, or
5 device;

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

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

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

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



1 Administration and remains under investigation in a United
2 States Food and Drug Administration-approved clinical trial.

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

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

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

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

16 (3) Clearly identifies the specific proposed
17 investigational drug, biological product, or device
18 that the patient is seeking to use;

19 (4) Describes the potentially best and worst outcomes of
20 using the investigational drug, biological product, or
21 device with a realistic description of the most likely



1 outcome, including the possibility that new,
2 unanticipated, different, or worse symptoms might
3 result, and that death could be hastened by the
4 proposed treatment, based on the physician's knowledge
5 of the proposed treatment in conjunction with an
6 awareness of the patient's condition;

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

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

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

18 (8) States that, except in cases of death as provided in
19 subsection (d), the patient understands that the
20 patient is liable for all expenses consequent to the



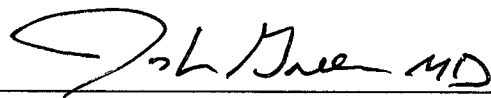
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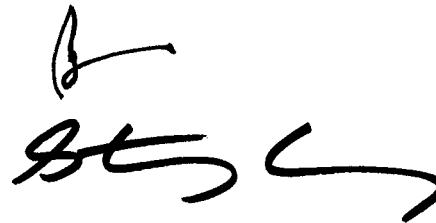
1 use of the investigational drug, biological product,
2 or device."

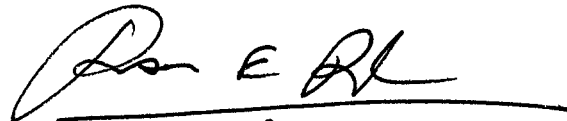
3 SECTION 3. New statutory material is underscored.

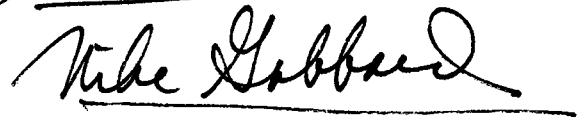
4 SECTION 4. This Act shall take effect on July 1, 2018.

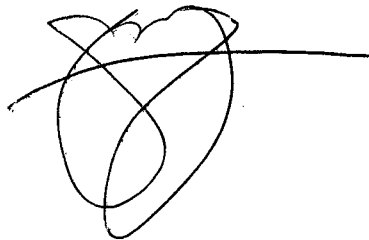
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INTRODUCED BY:













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Report Title:

Terminally Ill Patients; Investigational Drugs, Biological Products, or Devices; Access

Description:

Beginning January 1, 2019, allows manufacturers of investigational drugs, biological products, or devices to make available such drugs, products, or devices to terminally ill patients under certain conditions.

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