THE SENATE
TWENTY-EIGHTH LEGISLATURE, 2016
STATE OF HAWAII

S.B. NO. 2181

JAN 22 2016

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:

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

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

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

Several states, such as Arizona, Colorado, Louisiana, Michigan, and Missouri, have passed so-called "right-to-try" legislation that makes available experimental drugs without Food and Drug Administration approval to terminally ill patients with no other medication or treatment options.

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

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

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

"Eligible patient" means a person who has:

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

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

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

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

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

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

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

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

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

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

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

(2) Attests to the fact that the patient concurs with the patient's physician in believing that all currently

approved and conventionally recognized treatments are unlikely to prolong the patient's life;

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

(4) Describes the potentially best and worst outcomes of using the investigational drug, biological product, or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result, and that death could be hastened by the proposed treatment, based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

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

(6) Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and care may be reinstated if the curative

treatment ends and the patient meets hospice eligibility requirements;

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

(8) States that the patient understands that the patient is liable for all expenses consequent to the use of the investigational drug, biological product, or device, and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

(b) Beginning January 1, 2017, a manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients pursuant to this section. This section does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient. A manufacturer may:

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

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

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

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

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

(f) Notwithstanding any law to the contrary, a licensing board may not revoke, fail to renew, suspend, or take any action

against a health care provider's license based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, as long as the recommendations are consistent with medical standards of care. Action against a health care provider's medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device is prohibited.

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

(h) This section does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against another person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, for any harm done to the eligible patient resulting from the investigational drug,

biological product, or device, so long as the manufacturer or other person or entity is complying in good faith with the terms of this section, unless there was a failure to exercise reasonable care."

SECTION 3. New statutory material is underscored.

SECTION 4. This Act shall take effect on July 1, 2016.

INTRODUCED BY: Will Espero

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S.B. NO. 2181

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

Description:
Beginning January 1, 2017, 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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