HOUSE OF REPRESENTATIVES
THIRTY-SECOND LEGISLATURE, 2023
STATE OF HAWAII

H.B. NO. 966 H.D. 1

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 and biological products in the United States is intended to protect future patients from premature, ineffective, and unsafe medications and treatments, but the process often takes many years. Patients who have a terminal illness can be severely restricted in care options until an investigational drug or biological product receives final approval from the United States Food and Drug Administration.

The legislature further finds that because patients who have a terminal illness may often not have the time to wait for a potentially lifesaving investigational drug or biological product to gain final approval from the United States Food and Drug Administration, the federal government and forty-one states have enacted "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 grant terminally ill patients access to potentially life-saving investigational drugs and biological products that have not received final approval from the United States Food and Drug Administration.

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

"**§321- Access to investigational drugs and biological products for terminally ill patients.** (a) Notwithstanding section 328-17, beginning January 1, 2024, a manufacturer of an investigational drug or biological product may make available the manufacturer's investigational drug or biological product to eligible patients pursuant to this section.

(b) A manufacturer may:

(1) Provide an investigational drug or biological product 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 or biological product.

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

(d) An insurer may deny coverage to an eligible patient from the time the eligible patient begins use of the investigational drug or biological product through a period not to exceed six months from the time the eligible patient ceased to use the investigational drug or biological product; provided that coverage may not be denied for:

(1) A preexisting condition; or

(2) Coverage for benefits that commence prior to the time the eligible patient begins use of the investigational drug or biological product.

(e) If a patient dies while being treated by an investigational drug or biological product, the patient's heirs shall not be personally 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 on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug or biological product that is being developed to treat the type of terminal illness that afflicts the patient; any physical or psychological symptoms of the patient's terminal illness; or for palliative care. No action shall be taken against a health care provider's medicare certification based on the health care provider's recommendation that a patient have access to an investigational drug or biological product that is being developed to treat the type of terminal illness that afflicts the patient; any physical or psychological symptoms of the patient's terminal illness; or for palliative care.

(g) No official, employee, or agent of the State shall block or attempt to block an eligible patient's access to an investigational drug or biological product. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider shall not constitute a violation of this section.

(h) This section shall not create a private cause of action against a manufacturer of an investigational drug or biological product or against another person or entity involved in the care of an eligible patient using the investigational drug or biological product for any harm done to the eligible patient resulting from the investigational drug or biological product; provided that the manufacturer or other person or entity is complying in good faith with the requirements of this section; provided further that there was no failure to exercise reasonable care on the part of the manufacturer or other person or entity.

(i) Nothing in this section shall require that a manufacturer make available an investigational drug or biological product to an eligible patient.

(j) 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 treatment of the terminal illness located within one hundred miles of the patient's home address, 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 or biological product in order to treat the patient's terminal illness, physical or psychological symptoms of the patient's terminal illness, or for palliative care;

(5) Given written, informed consent for the use of the investigational drug or biological product 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 that

is regulated under section 321-11(10) or a public health facility under chapter 323F.

"Investigational drug or biological product" means a drug or biological product 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 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 or biological product that the patient is seeking to use;

(4) Describes the potentially best and worst outcomes of using the investigational drug or biological product 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 or biological product;

(6) Makes clear that the patient's eligibility for hospice care may be withdrawn by the hospice care provider 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 or biological product, and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug or biological product states otherwise."

SECTION 3. Section 328-17, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) [~~No~~] Except as provided in section 321- , no person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless [~~(1) an~~]:

(1) An application with respect [~~thereto~~] to the new drug has been approved and the approval has not been withdrawn under section 505 of the Federal Act[~~, or (2) when~~]; or

(2) When not subject to the Federal Act, unless the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed,

recommended, or suggested in the labeling [~~thereof,~~] of the drug, and prior to selling or offering for sale the drug, [~~there has been filed with the director of health~~] an application has been filed with the director of health setting forth [~~(A) full~~]:

(A) Full reports of investigations [~~which~~] that have been made to show whether or not the drug is safe for use and whether the drug is effective in use[~~; (B) a~~];

(B) A full list of the articles used as components of the drug[~~; (C) a~~];

(C) A full statement of the composition of the drug[~~; (D) a~~];

(D) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drugs[~~; (E) such~~];

(E) The samples of the drug and of the articles used as components [~~thereof~~] of the drug as the director may require[~~; and (F) specimens~~]; and

(F) Specimens of the labeling proposed to be used for the drug."

SECTION 4. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 5. This Act shall take effect on July 1, 3000.

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

Description:
Beginning on 1/1/2024, permits manufacturers of investigational drugs or biological products to make these drugs and products available to terminally ill patients under certain conditions. Effective 7/1/3000. (HD1)

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