THE SENATE
THIRTY-THIRD LEGISLATURE, 2025
STATE OF HAWAII

S.B. NO. 49

JAN 15 2025

A BILL FOR AN ACT

RELATING TO TERMINAL ILLNESSES.

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

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

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

Accordingly, the purpose of this Act is to enact similar "right-to-try" legislation in Hawaii by authorizing manufacturers of investigational drugs or biological products to make the drugs or products available to terminally ill patients under certain conditions.

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

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

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

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

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

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

(1) A preexisting condition; or

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

(d) If a patient dies while being treated with an investigational drug or biological product, the patient's heirs and estate shall not be liable for any outstanding debt related to the treatment, or for any balance not covered by health insurance.

(e) Notwithstanding any law to the contrary, no licensing board in the State shall revoke, fail to renew, suspend, or take any action against a health care provider's professional license or medicare certification based on the health care provider's recommendation to an eligible patient regarding access to or

treatment with an investigational drug or biological product that is being developed to:

(1) Treat the type of terminal illness that afflicts the patient;

(2) Ease the physical or psychological symptoms of the terminal illness; or

(3) For purposes of palliative care.

(f) 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 recommendations from a licensed health care provider that are consistent with medical standards of care shall not constitute a violation of this section.

(g) This section does not create a private cause of action against the manufacturer of an investigational drug or biological product, or against another person or entity involved in the care of an eligible patient who is using an investigative drug or biological product, for any harm to the eligible patient that results from the use of the investigational drug or biological product if the manufacturer, person, or entity

complied in good faith with the terms of this section and exercised reasonable care.

(h) For purposes of this section:

"Eligible patient" means a person who:

(1) Has been diagnosed with a terminal illness, attested to by the person's treating physician;

(2) Has considered all other reasonable treatment options currently approved for the person's condition by the United States Food and Drug Administration;

(3) Is unable to participate in a clinical trial for an investigational drug or biological product to treat the terminal illness within one hundred miles of the person's home address or has not been accepted to a clinical trial within one week of completing the clinical trial application process;

(4) Has a recommendation from the person's treating physician to try an investigational drug or biological product to treat the patient's terminal illness, ease physical or psychological symptoms of the terminal illness, or for purposes of palliative care;

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

(6) Provides documentation from the patient's treating physician that the patient meets the requirements of paragraphs (1) through (5).

"Eligible patient" does not include a person being treated:

(1) On an inpatient basis at an institution with an organized medical staff;

(2) At a facility regulated pursuant to section 321-11(10); or

(3) At a healthcare facility regulated pursuant to chapter 323F.

"Informed consent" means a written document signed by the eligible patient, or the eligible patient's legal representative, and attested to by the patient's treating physician, that:

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

(2) Attests to the fact that the treating physician finds, and the patient agrees, that no treatment listed in paragraph (1) is likely to prolong the patient's life;

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

(4) Describes, based on the treating physician's knowledge of the proposed treatment and the patient's condition, the possible best, worst, and most likely outcomes if the patient uses the investigational drug or biological product, including the possibility that the treatment may cause new, unanticipated, different, or exacerbated symptoms or that the treatment may hasten the patient's death; and

(5) States expressly that:

(A) The patient's health insurer and health care provider are not obligated to pay for any care or

treatment needed as a consequence of the investigational drug or biological product;

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

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

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

"Investigational drug or biological product" means a drug or biological product that has successfully completed phase one

of a clinical trial approved by the United States Food and Drug Administration but has not yet been cleared for general use.

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

SECTION 3. New statutory material is underscored.

SECTION 4. This Act shall take effect on January 1, 2026.

INTRODUCED BY: _____

S.B. NO. 49

Report Title:
FDA; 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 1/1/2026.

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