HOUSE OF REPRESENTATIVES
TWENTY-EIGHTH LEGISLATURE, 2015
STATE OF HAWAII

H.B. NO. 1013 H.D. 2

A BILL FOR AN ACT

RELATING TO EXPERIMENTAL TREATMENTS.

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

SECTION 1. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"CHAPTER

RIGHT TO TRY ACT

§ **-1 Title.** This chapter shall be known and may be cited as the "Right to Try Act".

§ **-2 Definitions.** As used in this chapter, and unless the context otherwise requires:

"Eligible patient" means an individual who meets all of the following conditions:

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

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

(3) Has received a recommendation from the individual's physician for an investigational drug, biological product, or device;

(4) Has given written, informed consent for the use of the investigational drug, biological product, or device; and

(5) Has documentation from the individual's physician that the individual meets the requirements of this chapter.

"Health care provider" means a health care professional listed under section 451D-2.

"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 progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with the administration of current United States

Food and Drug Administration-approved and available treatments, and that, without life-sustaining procedures, will soon result in death.

"Written, informed consent" means a written document that is signed by: the patient; the patient's parent, if the patient is a minor; or the patient's legal guardian, is attested to by the patient's physician and a witness and that, at a minimum, includes all of the following:

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

(2) An attestation 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) Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use;

(4) A description of the potentially best and worst outcomes of using the investigational drug, biological

product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(5) A statement that the patient's health plan or third party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless they are specifically required to do so by law or contract;

(6) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements; and

(7) A statement that the patient understands that the patient is liable for all expenses consequent to the use of the investigational drug, biological product, or device unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

§ -3 **Manufacturer responsibilities.** (a) A manufacturer of an investigational drug, biological product, or device may make available and an eligible patient may request the manufacturer's investigational drug, biological product, or device under this chapter; provided that a manufacturer shall not be required to make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may do any of the following:

(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.

§ -4 **Applicability to other laws.** This chapter shall not be construed to:

(1) Expand the coverage required of an insurer under article 10A of chapter 431, article 1 of chapter 432, or chapter 432D;

(2) Require a health plan, third party administrator, or governmental agency to provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use of an investigational drug, biological product, or device under this chapter;

(3) Require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device; or

(4) Require the provision of new or additional services by a hospital or facility that is licensed by the department of health under section 321-14.5, unless approved by the hospital or facility.

§ -5 **Claims against the patient's estate.** If a patient dies while being treated with an investigational drug, biological product, or device, the patient's heirs shall not be liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

§ -6 **Licensing and certification sanctions against health care providers.** (a) No licensing board shall revoke, fail to renew, suspend, or take any action against a health care provider, based solely upon the health care provider's recommendations to an eligible patient regarding access to, or treatment with, an investigational drug, biological product, or device.

(b) No entity responsible for medicare certification shall take action against a health care provider's medicare certification based solely upon the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

§ -7 **State intervention prohibited.** No official, employee, or agent of the State shall block or attempt to block an eligible patient's access to an investigational drug,

biological product, or device. Any counseling, advice, or recommendation consistent with medical standards of care from a licensed health care provider shall not constitute a violation of this section.

§ **-8 Private causes of action.** This chapter shall not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against any other 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, if the manufacturer or other person or entity complies in good faith with the terms of this chapter and has exercised reasonable care."

SECTION 2. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun before its effective date.

SECTION 3. This Act shall take effect on July 1, 2112.

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Report Title:
Right to Try Act; Experimental Treatments

Description:
Establishes the Right to Try Act. Authorizes manufacturers to make investigational drugs, biological products, or devices available to terminally ill patients who have given written, informed consent. Exempts from liability and sanctions, persons who are involved in a patient's participation in experimental treatments for terminal illness. Effective 7/1/2112. (HB1013 HD2)

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