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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2016

A N A C T

RELATING TO HEALTH AND SAFETY - TREATMENT FOR PATIENTS WITH TERMINAL ILLNESS--THE RHODE ISLAND TERMINALLY ILL PATIENTS' RIGHT TO TRY ACT OF 2016

Introduced By: Representatives McNamara, Shekarchi, Bennett, Diaz, and Serpa

Date Introduced: January 14, 2016

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

SECTION 1. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby amended by adding thereto the following chapter:

CHAPTER 94

TREATMENTS FOR PATIENTS WITH TERMINAL ILLNESS – THE RHODE ISLAND TERMINALLY ILL PATIENTS' RIGHT TO TRY ACT OF 2016

23-94-1. Short title - Treatments for patients with terminal illness. – This chapter shall be known and may be cited as the "Rhode Island Terminally Ill Patients' Right to Try Act of 2016".

23-94-2. Purpose. – The legislature finds that access to and the use of experimental treatments for patients with terminal illness will provide persons with the fundamental right to control the decisions relating to their own medical care. In order to respect these rights the legislature declares that the laws of the state shall recognize experimental treatments for patients with terminal illness and establish conditions for the use of experimental treatments.

23-94-3. Definitions. – (a) As used in this chapter, and unless the context otherwise requires:

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

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

(ii) Has considered all other treatment options currently approved by the Food and Drug

Administration;

(iii) Has received a recommendation from their physician for an investigational drug, biological product, or device;

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

(v) Has documentation from their physician that they meet the requirements of this section.

(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the Food and Drug Administration and remains under investigation in a Food and Drug Administration approved clinical trial.

(3) "Terminal illness," for purposes of this chapter, 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 administration of current federal drug administration approved and available treatments, and that, without life-sustaining procedures, will soon result in death.

(4) "Written informed consent" means a written document that is signed by:

(i) The patient;

(ii) The parent or legal guardian, if the patient is a minor;

(iii) Legal guardian; or

(iv) Patient advocate designated by the patient under the provisions of this title.

(b) Provided that, for purposes of this chapter, written informed consent must be attested to by the patient's physician and a witness and, 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 their 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 this treatment ends and the patient meets hospice eligibility requirements.

(7) A statement that the patient understands that they are liable for all expenses consequent to the use of the investigational drug, biological product, or device, but that this liability does not extend to the patient's estate.

23-94-4. Procedures. – (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. This chapter does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

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

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

(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.

23-94-5. Cost of services. – (a) This chapter does not expand the coverage required of an insurer pursuant to chapters 18, 19, 20, 20.1, or 41 of title 27.

(b) A health plan, third-party administrator, or governmental agency may, but is not required 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.

(c) This chapter does not 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.

(d) This chapter does not require a hospital or facility licensed pursuant to chapter 17 of this title to provide new or additional services, unless approved by the hospital or facility.

23-94-6. Treatment expenses liability. – Regardless of whether a patient dies while being treated by an investigational drug, biological product, or device, the patient's heirs and/or

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

23-94-7. Health care provider immunity. – A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a health care provider's license issued under this title, 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. An entity responsible for Medicare certification shall not take 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.

23-94-8. Patient access. – An official, employee, or agent of this 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.

23-94-9. Cause of action immunity. – (a) This chapter does 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 is complying in good faith with the terms of this chapter and has exercised reasonable care.

(b) This chapter does not affect any mandatory health care coverage for participation in clinical trials under the insurance provisions contained in this title or title 27.

23-94-10. Severability. – If any provisions of this chapter are declared unconstitutional, or the applicability of any provisions to any person or circumstance is held invalid, the constitutionality of the remainder of this chapter and its applicability to other persons and circumstances shall not be affected thereby.

SECTION 2. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO HEALTH AND SAFETY - TREATMENT FOR PATIENTS WITH TERMINAL ILLNESS--THE RHODE ISLAND TERMINALLY ILL PATIENTS' RIGHT TO TRY ACT OF 2016

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This act would create the "Rhode Island Terminally Ill Patient's Right to Try Act of 2016," which establishes the conditions for the use of experimental treatments for terminally ill patients.

This act would take effect upon passage.

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