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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. 2022

A N A C T

RELATING TO HEALTH AND SAFETY -- TREATMENT FOR PATIENTS WITH TERMINAL ILLNESS -- THE NEIL FACHON TERMINALLY ILL PATIENTS' RIGHT TO TRY ACT OF 2022

Introduced By: Representatives McNamara, and Caldwell

Date Introduced: February 09, 2022

Referred To: House Health & Human Services

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 97

TREATMENTS FOR PATIENTS WITH TERMINAL ILLNESS -- THE NEIL FACHON TERMINALLY ILL PATIENTS' RIGHT TO TRY ACT OF 2022

23-97-1. Short title - Treatments for patients with terminal illness.

This chapter shall be known and may be cited as the "Neil Fachon Terminally Ill Patients' Right To Try Act of 2022".

23-97-2. 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.

23-97-3. 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," 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 Food and 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 shall 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; and

(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.

23-97-4. 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.

23-97-5. 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.

23-97-6. 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 shall not be liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

23-97-7. 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.

23-97-8. Patient access.

(a) 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.

(b) A patient with a terminal diagnosis and condition within the ambits of this chapter has the right to try the use of an unconventional treatment that has demonstrated more safety and efficacy, through either trial research-based or anecdotal evidence, than standard conventional treatment.

23-97-9. Right to continue treatment.

A clinical trial patient has a right to continue the experimental treatment in a hospital setting, provided the patient or guardian signs a waiver of liability in favor of the hospital and its staff.

(1) Hospitals and nursing homes, or any other medical facility shall not suspend the treatment with medications associated with any clinical trial or experimental drug a patient was using before hospitalization or placement in another medical facility or nursing home.

(2) A patient's status as participating in a clinical trial or undergoing experimental treatment shall not be cited as the reason to prohibit access to any medical facility.

(3) The facility shall have the right to receive all information pertaining to the clinical trial/experimental treatment drug and may also require some training to administer that treatment. It shall be the responsibility of the provider of that treatment to provide the training on its administration.

(4) The facility shall be immune from any liability for any negative outcomes associated with continuing treatment.

(5) Notwithstanding the foregoing, a facility may withhold the experimental treatment when necessary for surgical procedures or when inquiring into potential negative interactions with

other drugs to be administered in the course of addressing the patient's other medical needs. In either instance, the experimental drug provider and/or physician shall be consulted in a timely fashion for their recommendations.

(6) A facility may advise discontinuation of experimental treatment when negative drug interactions are observed, and constitute a grave threat to the patient's life;

(i) In any conflict of opinion under this subsection, the provider of the experimental treatment shall determine when or if to discontinue treatment, except that the patient or the patient's guardian shall have the final decision on whether or not to continue treatment.

23-97-10. 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.

23-97-11. 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 NEIL FACHON TERMINALLY ILL PATIENTS' RIGHT TO TRY ACT OF 2022

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This act would create the "Neil Fachon Terminally Ill Patients' Right To Try Act of 2022," which establishes the conditions for the use of experimental treatments for terminally ill patients. Insurers would not be responsible to provide coverage for such treatment and the patient's heirs and/or estate would not be liable for any uninsured or underinsured costs associated with the treatment. The health care provider would be immune from liability or risk of the suspension of his or her license based solely on the provider's recommendation of treatment. The treatment may be provided in a hospital setting provided the patient signs a waiver of liability as to the hospital and its staff. The manufacturer of such treatment would be provided immunity provided they acted in good faith and exercised reasonable care.

This act would take effect upon passage.

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