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 2015

23-94-1. Short title. - Treatments for patients with terminal illness. – This chapter shall be known and may be cited as the "The Rhode Island Terminally Ill Patients’ Right to Try Act of 2015".

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) "Terminal illness", for purposes of this chapter, only, 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.

(2) "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 United States
Food and Drug Administration;

(iii) Has received a recommendation from his or her 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 his or her physician that he or she meets the requirements of
this section.

(3) "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 United States Food and Drug Administration and remains under
investigation in a United States Food and Drug Administration-approved clinical trial.

(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 his or her 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 he or she is liable for all expenses
consequent to the use of the investigational drug, biological product, or device and that this
liability extends to the patient's estate, unless a contract between the patient and the manufacturer
of the drug, biological product, or device states otherwise.

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.

(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. — If a patient dies while being treated by an
investigational drug, biological product, or device, the patient's heirs 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.
EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
AN ACT
RELATING TO HEALTH AND SAFETY - TREATMENT FOR PATIENTS WITH TERMINAL ILLNESS--THE RHODE ISLAND TERMINALLY ILL PATIENTS' RIGHT TO TRY ACT OF 2015

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1 This act would create the "Rhode Island Terminally Ill Patient's Right to Try Act of 2015," which establishes the conditions for the use of experimental treatments for terminally ill patients.

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4 This act would take effect upon passage.

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