CHAPTER 304
HB 701-FN - FINAL VERSION

26Mar2025... 0967h
05/15/2025 1986s
06/05/2025 2579s
26Jun2025... 2834CofC

2025 SESSION

25-0560
05/08

HOUSE BILL ***701-FN***

AN ACT relative to the terminal patients' right to try act.

SPONSORS: Rep. Mazur, Hills. 44; Rep. Alexander Jr., Hills. 29; Rep. Ammon, Hills. 42; Rep. Giasson, Hills. 29; Rep. Kofalt, Hills. 32; Rep. Layon, Rock. 13; Rep. Reinfurt, Hills. 29; Rep. Seidel, Hills. 29; Rep. Nalevanko, Ches. 9; Sen. Murphy, Dist 16; Sen. Sullivan, Dist 18

COMMITTEE: Health, Human Services and Elderly Affairs

AMENDED ANALYSIS

This bill allows for telehealth screening and remote signing in order to facilitate participation under the right to try act. The bill also narrows the scope of the act to terminal illness rather than life-threatening conditions.

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STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Twenty Five

AN ACT relative to the terminal patients' right to try act.

Be it Enacted by the Senate and House of Representatives in General Court convened:

304:1 Short Title. This act shall be known as the John Lewicke and Michael Yakubovich Right to Try Act.

304:2 Terminal Patients' Right to Try Act; Definitions. Amend RSA 126-Z:1 to read as follows:

126-Z:1 Definitions. In this chapter:

I. ***"Eligible facility" means a licensed New Hampshire institution that is operating under a Federalwide Assurance ("FWA") for the Protection of Human Subjects under 42 U.S.C. section 289(a) and 45 C.F.R. part 46. Any eligible facility is subject to the FWA laws, regulations, policies, and guidelines including renewals or updates.***

I-a. "Eligible patient" means a person to whom all of the following apply:

(a) The person has been diagnosed ***with a terminal illness*** by the person's physician ~~[with a life-threatening disease or condition~~].

(b) The person has already tried or is not a candidate for eligible United States Food and Drug Administration (FDA) approved treatment options for their disease or condition.

(c) The person is unable to participate in a clinical trial involving the eligible investigational drug, biologic or device.

(d) The person has given written informed consent for the use of the investigational drug, biological product, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written informed consent on the patient's behalf.

(e) The physician providing access to an investigational drug, biologic, or device will not be compensated directly by the manufacturer for providing access to this therapy.

I-b. "Health care provider" means a physician licensed to practice medicine in the state of New Hampshire.

I-c. "Individualized investigational treatment" means drugs, biologics, or devices unique to and produced exclusively for use for an individual patient, based on their own genetic profile, including but not limited to individualized gene therapy antisense oligonucleotides (ASO), individualized neoantigen vaccines, and any other individualized treatment.

II. "Investigational drug, biologic, or device" means a drug, biologic, or device that has successfully completed phase one of a clinical trial, but has not been approved for general use by the FDA and remains under investigation in a clinical trial.

II-a. [~~"Life-threatening disease" means:~~

~~(a) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and~~

~~(b) Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis for new drugs, biologics, or devices for that disease or condition is survival.~~

~~II-b.~~] "Other protected access" includes:

(a) "Expanded access" whereby the treating physician requests access to an investigational drug, biologic, or device from the FDA and is subject to oversight from an Institutional Review Board; and

(b) "Off-label use" means prescribing an FDA approved drug, biologic, or device for a use not approved for that specific indication consistent with RSA 329:17, VI-b.

III. "Physician" means the licensed *allopathic or osteopathic* physician who is providing medical care or treatment to the eligible patient for the terminal illness.

IV. "Remote signing" means the signing of any form, witnessed by a notary public or a licensed health care provider, providing written informed consent for a person diagnosed by a physician with a terminal illness to participate in a clinical trial or receive a drug, biologic, or device, by the patient or, if the patient is a minor or lacks the mental capacity to provide consent, by a parent or legal guardian on the patient's behalf.

V. "Telehealth prescreening" means any remote, real-time discussion intended, in part, to determine whether a person with a terminal illness may be:

(a) Ineligible for or not selected to participate in a clinical trial; or

(b) Ineligible to receive or not be offered a drug, biologic, or device.

VI. "Terminal illness" means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted, and diseases or conditions with potentially fatal outcomes, where the endpoint of a clinical trial analysis is survival, which is the definition of "life threatening" under 21 C.F.R. section 312.81.

304:3 New Paragraph; Terminal Patients' Right to Try Act; Liability of Physician. Amend RSA 126-Z:3 by inserting after paragraph II the following new paragraph:

III. Notwithstanding any provision of law to the contrary, a manufacturer of a drug, biologic, or device, a pharmacist, a health care facility, a health care provider, or a person or entity involved in the care of a patient using a drug, biologic, or device is immune from suit for any harm done to a patient resulting from the drug, biologic, or device if:

(a) The person has a terminal illness as determined by the person's physician and a consulting physician;

(b) The person's physician has determined that the person has no comparable or satisfactory United States Food and Drug Administration (FDA) approved treatment options available to treat the disease or condition involved;

(c) The patient has given written informed consent for the use of the drug, biologic, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written informed consent on the patient's behalf and, if the patient is a legal adult, the consent is not contrary to the prior documented wishes of the patient;

(d) The manufacturer, pharmacist, facility, provider, or other person or entity has not engaged in willful or reckless misconduct or other bad faith conduct. "Willful or reckless misconduct" shall include, but is not limited to, any conduct intended to hasten the death of the patient; and

(e) If the drug, biologic, or device is an individualized investigational treatment, it is administered by a health care provider at an eligible facility.

304:4 Private Cause of Action. Amend RSA 126-Z:4 to read as follows:

126-Z:4 Private Cause of Action.

I. Nothing in this chapter shall be construed to create a private cause of action against [~~a manufacturer of an investigational drug, biologic, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biologic, or device for any harm done to the eligible patient resulting from the investigational drug, biologic, 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~~] *any person or entity except as specified in paragraph II.*

II. Notwithstanding any provision of law to the contrary, any patient diagnosed with a terminal illness by a physician, and who has been treated, is being treated, or otherwise could be treated in New Hampshire with a drug, biologic, or device, and is affected by a violation of this chapter, or a health care facility or a health care provider involved in the treatment of the patient, shall be entitled to petition the superior court for injunctive relief and reasonable attorney's fees against any regulatory or law enforcement authority that violates this chapter.

304:5 New Sections; Telehealth Prescreening and Remote Signing. Amend RSA 126-Z by inserting after section 5 the following new sections:

126-Z:6 Telehealth Prescreening.

I. Notwithstanding any regulation or provision of law to the contrary, any health care provider, while physically located in New Hampshire, may conduct a telehealth prescreening with any patient, in any state or jurisdiction, who has been diagnosed by a physician with a terminal illness.

II. No regulatory or law enforcement agency or subdivision shall take action against a health care facility, a health care provider, or a person or entity involved in the care of a patient for conducting a telehealth prescreening as defined in this chapter and pursuant to paragraph I.

III. A health care facility, a health care provider, or a person or entity involved in the care of a patient shall be immune from suit to the extent that the suit is based upon a telehealth prescreening.

126-Z:7 Remote Signing.

I. Notwithstanding any regulation or provision of law to the contrary, a manufacturer of a drug, biologic, or device, a pharmacist, a health care facility, a health care provider, or a person or entity involved in the care of a patient using a drug, biologic, or device may obtain consent to treat a patient using remote signing as defined in this chapter, provided that the manufacturer, pharmacist, facility, provider, or other person or entity has an office in the state of New Hampshire and has conducted a telehealth prescreening pursuant to RSA 126-Z:1, IV. The remote signing shall amount to full and effective consent for treatment under all applicable laws and regulations.

II. No regulatory or law enforcement agency or subdivision shall take action against a health care facility, a health care provider, or a person or entity involved in the care of a patient for obtaining patient consent through remote signing, as defined in this chapter, if the provider or facility has complied with paragraph I.

III. A health care facility, a health care provider, or a person or entity involved in the care of a patient shall be immune from suit to the extent that the suit challenges the validity of a remote signing to effect lawful consent, provided that the person or entity is complying in good faith with the terms of this chapter and has not engaged in willful misconduct.

126-Z:8 Statutory Construction. The general court enacts this chapter to promote maximum access by removing barriers in state law and indemnifying those involved in providing potentially life-saving treatments and treatments to improve the quality of patients' remaining life, to incentivize health care facilities, health care providers, manufacturers of drugs, biologics and/or devices, and other persons and entities involved in the care of patients, to treat terminal illness, whether through company-sponsored clinical trial, single-patient protocol, compassionate use protocol, or any other means of access to drugs, biologics, and/or devices which gathers information on patient outcomes, and to make New Hampshire a jurisdiction that attracts and fosters clinical trials and the development of drugs, biologics, and devices intended to treat terminal illness. This chapter shall be construed consistently with the general court's stated purpose.

304:6 New Paragraph; Availability of Investigational Drugs, Biologics, or Devices; Costs; Coverage. Amend RSA 126-Z:2 by inserting after paragraph III the following new paragraph:

IV. Nothing in this chapter shall require a health care provider, health care facility, or the manufacturer of an investigational drug, biological product, or device, to make an experimental treatment available to an eligible patient.

304:7 Effective Date. This act shall take effect January 1, 2026.

Approved: August 20, 2025
Effective Date: January 01, 2026