Rep. Packard, Rock. 16
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May 13, 2026
2026-1951h
09/08

Floor Amendment to SB 504

Amend the title of the bill by replacing it with the following:

AN ACT relative to the practice of pharmacy and the dispensing of certain medications by pharmacists, authorizing the establishment of experimental treatment centers, and permitting treatment of certain severe illness under the right to try act.

Amend the bill by replacing all after section 13 with the following:

14 Short Title. Sections 14 through 16 of this act shall be known as the "John Lewicke and Michael Yakubovich Experimental Treatment Centers Act".

15 New Chapter; Experimental Treatment Centers. Amend RSA by inserting after chapter 126-Z the following new chapter:

CHAPTER 126-ZZ

EXPERIMENTAL TREATMENT CENTERS

126-ZZ:1 Statement of Intent.

The general court enacts this chapter to promote maximum access to innovative health care by removing legal barriers to cutting-edge treatments and to make New Hampshire a jurisdiction that attracts and fosters clinical trials and the development of drugs, biologics, and devices intended to combat illness and promote human flourishing. This chapter shall be construed consistently with the general court's stated purpose.

126-ZZ:2 Definitions.

In this chapter:

I. “Eligible patient” means a person to whom all of the following apply:

(a) The person has received a recommendation from the patient's treating physician for an experimental treatment;

(b) The physician certifies in writing that they have provided the recommendation and that the patient has considered alternative treatments approved by the FDA; and

(c) The person has given written informed consent for use of the experimental treatment, including at least the following information:

(1) Clear identification of the specific experimental treatment sought by the patient;

(2) Certification that the patient and physician have discussed whether there are any applicable FDA-approved treatments and, if so, the nature of such treatments;

(3) Certification that the patient and physician have discussed best and worst outcomes from the treatment and the most likely outcome based on available data;

(4) An acknowledgment that insurance is not obligated to pay for treatment or consequent care;

(5) A statement, if applicable, that patient is liable for treatment expenses; and

(6) A prominent statement that the patient is seeking treatment from an experimental treatment center under RSA 126-ZZ.

II. "Experimental treatment" means the provision of a medical intervention by a health care provider involving an investigational drug, biologic, or device that has successfully completed phase one of a clinical trial, but is not yet FDA-approved for general use and either:

(a) Remains under investigation in a clinical trial; or

(b) Has a demonstrated safety record through documented clinical evidence from a qualified medical institution as defined in paragraph VI. For the purposes of this provision, "qualified medical institution" may be further defined by the department of health and human services through a rulemaking under RSA 541-A.

III. "Experimental treatment center" means a health care provider, whether a business or nonprofit, that administers experimental therapies pursuant to RSA 126-ZZ:3. An entity's status as an experimental treatment center under this chapter is legally distinct from its licensing status under RSA 151:2, its administration of any treatments under 126-Z, and its participation in other protected access.

IV. "Other protected access" includes expanded access or compassionate use, in which the treating physician has requested access under 21 C.F.R. Part 312, Subpart I and other applicable FDA regulations or off-label use consistent with the physician's professional obligations under RSA 329.

V. "Physician" means the licensed allopathic or osteopathic physician providing medical care or treatment to the patient.

VI. "Qualified medical institution" means an institution that has generated documented clinical evidence supporting the safety of a medical intervention equivalent to that required for successful completion of a phase I clinical trial, and operates under one of the following frameworks:

(a) Oversight by a regulatory authority recognized by international standards; or

(b) Oversight by a regulatory authority that demonstrates substantially equivalent standards for data quality, monitoring, and patient protection as determined by the experimental treatment center's scientific review board.

126-ZZ:3 Availability of Investigational Drugs, Biologics, or Devices.

I. A manufacturer of a drug, biologic, or device used in experimental treatments or an experimental treatment center may make available the drug, biologic, or device to eligible patients pursuant to this chapter. The manufacturer or treatment center may:

(a) Provide the drug, biologic, or device to an eligible patient without compensation; or

(b) Require the eligible patient to pay for the treatment and establish payment arrangements with the patient; and

(c) Ask eligible patients to participate in data collection relating to the use of the drug, biologic, or device.

II. Nothing in this chapter requires a health care insurer or any state agency to provide coverage for any experimental treatment.

III. Nothing in this chapter requires the manufacturer of an experimental treatment to include a patient in any particular clinical trial or study.

IV. Nothing in this chapter requires a health care provider or manufacturer to make an experimental treatment available to any eligible patient.

V. Nothing in this chapter shall prohibit an experimental treatment center from conducting clinical research protocols. Clinical research protocols may be approved by an institutional review board (IRB) meeting pursuant to 45 C.F.R. Part 46 or by a scientific review board established under this chapter. Research protocols may employ any study design, participant stratification, outcome measurement, or monitoring approach consistent with the protocol's scientific and ethical justification. Clinical research conducted under this section shall maintain all study records, including protocols, consent forms, case reports, and safety data, for not less than 3 years and shall make such records available to state or federal regulatory authorities upon reasonable request or where disclosure is required by law or regulation. Sites conducting research under this chapter consent to inspection by state or federal regulatory authorities, at reasonable times and upon reasonable request, as necessary to verify compliance with applicable requirements.

126-ZZ:4 Limitation on State or Political Subdivision Action.

I. Notwithstanding any provision of law to the contrary, the board of medicine shall not revoke, fail to renew, or take any other action against a physician's license issued pursuant to RSA 329, or any other law, based primarily on a physician's recommendation to an eligible patient regarding or prescription for treatment under this chapter.

II. Notwithstanding any provision of law to the contrary, the department of health and human services shall not take action against a provider licensed under RSA 151, or any other law, based primarily on the institution's participation in treatment authorized under this chapter.

126-ZZ:5 Experimental Treatment Center Licensing.

I. A provider seeking to provide experimental treatments under this chapter, including but not limited to a health care facility licensed under RSA 151, shall obtain experimental treatment center authorization from the department of health and human services.

II. The authorization fee shall be $2,500 initially and $1,250 annually for facilities already licensed under RSA 151, and $10,000 initially and $5,000 annually for entities not otherwise licensed.

III. To obtain authorization from the department, applicants shall have a medical director who is a physician licensed to practice medicine in New Hampshire. If the department promulgates a rule governing adverse event reporting procedures, experimental treatment centers have an ongoing obligation to demonstrate compliance with that rule.

IV. Authorized providers may administer experimental treatments to eligible patients pursuant to RSA 126-ZZ:2, II if reviewed and approved by a scientific review board established under this chapter. The scientific review board shall determine the appropriate quality standards, documentation requirements, and clinical oversight for each treatment protocol, which may include quality frameworks and documentation standards recognized by international regulatory authorities. The scientific review board shall include not fewer than 3 members with appropriate expertise and shall include at least one licensed physician and at least one member with experience in clinical outcomes research. Providers may share scientific review boards or board members with other authorized facilities or with academic institutions.

V. Notwithstanding any law or regulation to the contrary, health care facilities currently licensed under RSA 151 may add experimental treatment center services by obtaining authorization under this section without otherwise obtaining additional licensing.

VI. Notwithstanding any law or regulation to the contrary, authorized experimental treatment centers may establish payment arrangements with patients, including direct pay, subscription models, membership fees, or other payment structures, including digital currencies, with or without regard to insurance coverage requirements.

VII. Notwithstanding any law or regulation to the contrary, services provided by authorized experimental treatment centers under this chapter are exempt from any state insurance coverage mandates, network adequacy requirements, and prior authorization procedures.

VIII. The commissioner may adopt rules under RSA 541-A establishing minimum standards for scientific review boards, adverse event reporting, and authorization procedures.

IX. A company operating an experimental treatment center in New Hampshire shall be eligible to apply for the research and development tax credit under RSA 77-A:5, XIII.

X. The commissioner may also enter into reciprocal agreements with other states or their similar agencies for cross-border treatment coordination and shared scientific review board recognition. The department shall issue experimental treatment center licenses to applicants

already licensed under another state's substantially similar law, provided the applicant satisfies paragraph IV in New Hampshire. A state's law is presumptively "substantially similar" to New Hampshire's if it provides for the licensure of experimental treatment centers requiring approval of treatment protocols and assessment of experimental treatment for patient safety by scientific review boards.

126-ZZ:6 Manufacturing

I. Authorized experimental treatment centers may manufacture drugs, biologics, or devices on-site or through contracted facilities, provided the center's scientific review board approves the manufacturing protocol and determines it meets quality standards equivalent to recognized pharmaceutical manufacturing frameworks for patient safety. The scientific review board shall determine the appropriate quality framework for manufacturing and compounding under this chapter for purposes of clinical use in experimental treatment centers.

II. The scientific review board shall document its rationale for approving manufacturing facilities and protocols, including comparison to recognized industry standards such as good manufacturing practice or international organization for standardization frameworks.

III. Batch and distribution records shall be maintained for each lot and provided to the department within fifteen days upon request. The experimental treatment center shall maintain such records for a minimum of two years.

IV. The commissioner may adopt rules under RSA 541-A establishing manufacturing standards and quality requirements, including rules to enforce the requirements of this section.

V. Nothing in this section shall be construed to alter the jurisdiction or authority of the board of pharmacy under RSA 318.

126-ZZ:7 Free Care and Public Benefits.

I. Each licensed experimental treatment center shall allocate 2 percent of its net annual profits to support access to experimental treatments and health care for qualifying New Hampshire residents. The center shall document and report this allocation on a form provided by the department, if the department provides such a form. Documentation and reporting shall be submitted no later than February 1 of each year.

II. The requirement in paragraph I may be fulfilled by one or a combination of the following:

(a) Providing experimental treatment, as defined in this chapter, for free to qualifying New Hampshire residents who are eligible patients in an amount equal to at least 2 percent of the center's net annual profits; or

(b) Contributing an amount equal to at least 2 percent of the center's net annual profits the uncompensated care fund established under RSA 167:64, the opioid abatement trust fund established under RSA 126-A:84, the alcohol abuse prevention and treatment fund established under RSA 176-A:1, the lead paint poisoning control fund established under RSA 130-A:15, or any fund to benefit the developmentally disabled established under RSA 171-A:8-b, provided that the

department may adjudicate in a rulemaking under RSA 541-A that one or more of these funds is functionally inactive and therefore ineligible to satisfy the requirements of this provision.

III. The commissioner of the department of health and human services shall adopt rules, pursuant to RSA 541-A, establishing criteria for identifying "qualifying New Hampshire residents" eligible to receive free experimental treatment under subparagraph II(a). Such rules may consider factors including income level, insurance status, and medical need.

IV. The department may adopt rules and develop procedures to review and approve documentation under this section and ensure that required allocations are made annually.

16 New Subparagraph; Health Care Facility Licensing; Exemptions; Experimental Treatment Center. Amend RSA 151:2, II as follows by inserting after subparagraph (i) the following new subparagraph:

(j) To the extent that a provider operates as an experimental treatment center defined in RSA 126-ZZ, operating under that chapter and in compliance with all review and patient protection standards described therein, it shall not be required to obtain a license except as provided in that chapter.

17 Right to Try Act. Amend RSA 126-Z:1 through 126-Z:4 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.~~

~~(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.~~] ***I-b.*** "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.~~] "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 ***or qualifying severe*** illness.

III-a.(a) "Qualifying severe illness" means an illness that is both chronic and debilitating.

(b) "Chronic and debilitating" shall have the same meaning as "severely debilitating" defined under 21 C.F.R. 312.81(b).

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 ***or qualifying severe*** 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 ***or qualifying severe*** 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.

126-Z:2 Availability of Investigational Drugs, Biologics, or Devices; Costs; Coverage.

I. A manufacturer [~~of an investigational drug, biologic, or device~~] may make [~~available an investigational~~] ***a*** drug, biologic, or device [~~to eligible patients pursuant to this chapter. A manufacturer may:~~] ***not approved by the United States Food and Drug Administration available to patients if the requirements of RSA 126-Z:3, III are satisfied.***

I-a. Pursuant to this chapter, a manufacturer may:

(a) Provide [~~an investigational~~] ***a*** drug, biologic, or device to [~~an eligible~~] ***a*** patient without receiving compensation.

(b) Require [~~an eligible~~] ***a*** patient to pay [~~the costs of or associated with the manufacture of the investigational~~] ***for the treatment and establish payment arrangements for the*** drug, biologic, or device.

(c) Require [~~an eligible~~] ***a*** patient to participate in data collection relating to the use of the [~~investigational~~] drug, biologic, or device.

II. This chapter shall not require a health care insurer or any state agency to provide coverage for the cost of any [~~investigational~~] drug, biologic, or device.

III. Nothing in this chapter shall require the manufacturer of [~~an investigational~~] ***a*** drug, biologic, or device to include [~~an eligible~~] ***a*** patient in a particular clinical trial or study.

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

126-Z:3 Liability of Physician; Facility.

I. Notwithstanding any provision of law to the contrary, the board of medicine shall not revoke, fail to renew, or take any other action against a physician's license issued pursuant to RSA 329 based primarily on a physician's recommendation to [~~an eligible~~] ***a*** patient regarding or prescription for or treatment with [~~an investigational~~] ***a*** drug, biologic, or device ***pursuant to this chapter***.

II. Notwithstanding any provision of law to the contrary, the department of health and human services shall not take action against a facility licensed under RSA 151 based primarily on the institution's participation in the treatment or use of [~~an investigational~~] ***a*** drug, biologic, or device under this chapter.

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 ***or qualifying severe*** 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 not approved by the FDA 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~~] ***in cooperation with*** an eligible facility.

126-Z:4 Private Cause of Action.

I. Nothing in this chapter shall be construed to create a private cause of action against 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 ***or qualifying severe*** 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.

18 Telehealth Prescreening. Amend RSA 126-Z:6, I to read as follows:

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 ***or qualifying severe*** illness.

19 Statutory Construction. Amend RSA 126-Z:8 to read as follows:

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 ***or dramatically life-improving*** 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 ***and qualifying severe*** 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 ***and qualifying severe*** illness. This chapter shall be construed consistently with the general court's stated purpose.

20 Effective Date.

I. Sections 14 - 16 of this act shall take effect January 1, 2027.

II. Sections 1 - 13 of this act shall take effect 60 days after its passage.

III. The remainder of this act shall take effect upon its passage.

2026-1951h

AMENDED ANALYSIS

This bill:

I. Authorizes the dispensing of up to a 30-day supply of noncontrolled oral anti-cancer medication by a licensed health care professional legally authorized to prescribe and administer medications to a patient under a provider's care or supervision subject to certain conditions.

II. Amends the display requirements for certain licenses and permits.

III. Authorizes licensed advanced pharmacy technicians to engage in remote processing.

IV. Removes the requirement that a pharmacist's name or initials be on a label affixed to any controlled drug or prescription issued.

V. Amends the definition of the "practice of pharmacy."

VI. Removes certain authority of the board of pharmacy with respect to the regulation of collaborative pharmacy practice agreements.

VII. Limits any examination requirement for licensure as an advanced pharmacy technician to scope of practice.

VIII. Prohibits the pharmacy board from testing applicants on pharmacy jurisprudence or law.

IX. Allows supervised certified pharmacy technicians to administer vaccines, and eliminates a requirement that vaccines be recommended by the United States Center for Disease Control and Prevention Advisory Committee on Immunization Practices before being administered by pharmacists, pharmacy interns, licensed advanced pharmacy technicians, or certified pharmacy technicians.

X. Permits the establishment of experimental treatment centers. The centers would be authorized by the department of health and human services to provide treatment involving an investigational drug, biologic, or device that has successfully completed phase one of a clinical trial, but is not yet FDA-approved for general use and either remains under investigation in a clinical trial or has a demonstrated safety record from a qualified medical institution.

XI. Permits treatment of certain severe illness under the right to try act.