HB 1734-FN - AS INTRODUCED

2026 SESSION

26-2801
05/06

HOUSE BILL ***1734-FN***

AN ACT authorizing the establishment of experimental treatment centers.

SPONSORS: Rep. Kesselring, Hills. 18; Rep. Cole, Hills. 26; Rep. Mazur, Hills. 44; Rep. Polozov, Merr. 10; Rep. D. McGuire, Merr. 14; Rep. Markell, Rock. 18; Rep. Bernardy, Rock. 36; Rep. Kofalt, Hills. 32; Rep. Osborne, Rock. 2; Rep. Miles, Hills. 12; Sen. Murphy, Dist 16; Sen. Sullivan, Dist 18; Sen. Innis, Dist 7; Sen. McGough, Dist 11

COMMITTEE: Health, Human Services and Elderly Affairs

ANALYSIS

This bill 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.

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Explanation: Matter added to current law appears in ***bold italics.***
Matter removed from current law appears [~~in brackets and struckthrough.~~]
Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

26-2801
05/06

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Twenty-Six

AN ACT authorizing the establishment of experimental treatment centers.

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

1 Short Title. This act shall be known as the "John Lewicke and Michael Yakubovich Experimental Treatment Centers Act".

2 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.

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. Experimental treatment centers may only administer therapies that are approved by an active scientific review board. A scientific review board shall either be established by the experimental treatment center or independently contracted and shall include not fewer than 3 members with appropriate expertise, including at least one physician qualified to practice medicine in New Hampshire and at least one member with experience in clinical outcomes research. Providers may share 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.

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.

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.

3 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.

4 Effective Date. This act shall take effect January 1, 2027.

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HB 1734-FN- FISAL NOTE
AS INTRODUCED

AN ACT authorizing the establishment of experimental treatment centers.

FISCAL IMPACT:

The Legislative Budget Assistant has determined that this legislation has a total fiscal impact of less than $10,000 in each of the fiscal years 2026 through 2029.

AGENCIES CONTACTED:

Department of Health and Human Services