

HB 1734-FN - AS AMENDED BY THE HOUSE

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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.

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Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

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

3 2 New Chapter; Experimental Treatment Centers. Amend RSA by inserting after chapter 126-Z
4 the following new chapter:

5 CHAPTER 126-ZZ

6 EXPERIMENTAL TREATMENT CENTERS

7 126-ZZ:1 Statement of Intent.

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

13 126-ZZ:2 Definitions.

14 In this chapter:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 IV. “Other protected access” includes expanded access or compassionate use, in which the
15 treating physician has requested access under 21 C.F.R. Part 312, Subpart I and other applicable
16 FDA regulations or off-label use consistent with the physician’s professional obligations under RSA
17 329.

18 V. “Physician” means the licensed allopathic or osteopathic physician providing medical care
19 or treatment to the patient.

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

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

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

27 126-ZZ:3 Availability of Investigational Drugs, Biologics, or Devices.

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

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

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

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

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

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

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

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

16 126-ZZ:4 Limitation on State or Political Subdivision Action.

17 I. Notwithstanding any provision of law to the contrary, the board of medicine shall not
18 revoke, fail to renew, or take any other action against a physician's license issued pursuant to RSA
19 329, or any other law, based primarily on a physician's recommendation to an eligible patient
20 regarding or prescription for treatment under this chapter.

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

24 126-ZZ:5 Experimental Treatment Center Licensing.

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

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

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

35 IV. Authorized providers may administer experimental treatments to eligible patients
36 pursuant to RSA 126-ZZ:2, II if reviewed and approved by a scientific review board established
37 under this chapter. The scientific review board shall determine the appropriate quality standards,

1 documentation requirements, and clinical oversight for each treatment protocol, which may include
2 quality frameworks and documentation standards recognized by international regulatory
3 authorities. The scientific review board shall include not fewer than 3 members with appropriate
4 expertise and shall include at least one licensed physician and at least one member with experience
5 in clinical outcomes research. Providers may share scientific review boards or board members with
6 other authorized facilities or with academic institutions.

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

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

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

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

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

21 X. The commissioner may also enter into reciprocal agreements with other states or their
22 similar agencies for cross-border treatment coordination and shared scientific review board
23 recognition. The department shall issue experimental treatment center licenses to applicants
24 already licensed under another state's substantially similar law, provided the applicant satisfies
25 paragraph IV in New Hampshire. A state's law is presumptively "substantially similar" to New
26 Hampshire's if it provides for the licensure of experimental treatment centers requiring approval of
27 treatment protocols and assessment of experimental treatment for patient safety by scientific review
28 boards.

29 126-ZZ:6 Manufacturing

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

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

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

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

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

11 126-ZZ:7 Free Care and Public Benefits.

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

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

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

21 (b) Contributing an amount equal to at least 2 percent of the center's net annual profits
22 the uncompensated care fund established under RSA 167:64, the opioid abatement trust fund
23 established under RSA 126-A:84, the alcohol abuse prevention and treatment fund established under
24 RSA 176-A:1, the lead paint poisoning control fund established under RSA 130-A:15, or any fund to
25 benefit the developmentally disabled established under RSA 171-A:8-b, provided that the
26 department may adjudicate in a rulemaking under RSA 541-A that one or more of these funds is
27 functionally inactive and therefore ineligible to satisfy the requirements of this provision.

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

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

34 3 New Subparagraph; Health Care Facility Licensing; Exemptions; Experimental Treatment
35 Center. Amend RSA 151:2, II as follows by inserting after subparagraph (i) the following new
36 subparagraph:

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

5 4 Effective Date. This act shall take effect January 1, 2027.

HB 1734-FN- FISCAL NOTE
 AS AMENDED BY THE HOUSE (AMENDMENT #2026-0666h)

AN ACT authorizing the establishment of experimental treatment centers.

FISCAL IMPACT: This bill does not provide funding, nor does it authorize new positions.

Estimated State Impact				
	FY 2026	FY 2027	FY 2028	FY 2029
Revenue	\$0	Indeterminable	Indeterminable	Indeterminable
<i>Revenue Fund(s)</i>	General fund			
Expenditures*	\$0	\$2.5 million+	\$1 million+	\$1 million+
<i>Funding Source(s)</i>	General fund			
Appropriations*	\$0	\$0	\$0	\$0
<i>Funding Source(s)</i>	None			

***Expenditure = Cost of bill**

***Appropriation = Authorized funding to cover cost of bill**

METHODOLOGY:

This bill establishes a process for the licensure and regulation of experimental treatment centers. The bill permits health care providers to offer medical interventions involving investigational drugs, biologics, or devices that have successfully completed phase I of a clinical trial but are not yet FDA-approved for general use, and makes the Department of Health and Human Services responsible for oversight of these entities.

The Office of the Legislative Budget Assistant notes that previous versions of this fiscal note, including the initial version for the bill as amended by the House, identified a fiscal impact of less than \$10,000 per year. Subsequent to the issuance of those fiscal notes, the Department of Health and Human Services re-assessed the bill's impact on its operations, resulting in a significantly greater cost estimate. The analysis that follows is based on the Department's re-assessment.

The Department assumes that, in order to handle the new responsibilities created by the bill, it will need to establish a new bureau or unit responsible for licensing and regulating experimental treatment centers. This will further necessitate the development and implementation of a new set of administrative rules specific to these centers. Because the bill creates a new chapter of law, the Department is unclear how the new responsibilities will connect to the statutory requirements of RSA 151, the state's health facilities licensing statute. At a minimum, this is

expected to involve the creation of a new licensing category and minimum standards for scientific review boards, not currently known to or understood by the Department.

The Department anticipates a need for new personnel, as well as a contracted consultant with expertise in investigational drugs, biologics, or devices that have successfully completed phase I of a clinical trial but are not yet FDA-approved. For FY27, salaries for three staff members—two administrative and investigative positions plus a supervisor—are estimated at \$465,000, while an expert consultant specializing in investigational treatments would cost an additional \$250,000, for a total of \$715,000. In FY28, staff salaries would rise to \$489,000, with the consultant's fee dropping to \$75,000, totaling \$564,000. By FY29, staff salaries are projected at \$513,000 and the consultant's fee remains at \$75,000, making the year's total \$588,000.

The Department assumes it will need the following resources for initial and ongoing IT costs:

- System Development (Application + Database): \$1.0 million.
- Labor Costs up to \$950,000 for Year 1 (Plus additional labor for following years, depending on programmatic need). This figure assumes the following positions/consultants will be necessary: Technical Lead (1), Developers (2-3), Database/Application Administrator (1/2-1), Business Analyst (1), QA/Tester (1), Project Manager (shared/part-time).
- Data Storage and Hosting: \$50,000 – \$150,000 annually
- Annual Operating Costs, including user support and help desk, vendor licensing fees (if using a platform), cloud hosting and storage, routine enhancements, system monitoring and cyber security updates: \$250,000 – \$450,000 per year

Finally, the Department expects to need an additional \$550,000 in FY27 and some indeterminable amount in subsequent years for office space and equipment, as well as general operating costs such as office utilities, supplies, printing, legal and hearing costs, outreach and stakeholder engagement, and travel.

Combined, these estimates assume first-year costs of approximately \$2.5 million, and ongoing costs of \$1 million or more. The bill does allow for the following authorization fees for experimental treatment centers \$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 under RSA 151. While these fees will result in an increase in state revenue, the number of entities that may seek authorization is unknown, and so the resulting revenue increase is indeterminable.

AGENCIES CONTACTED:

Department of Health and Human Services