

Amended to Amended -- establishing a committee to study the feasibility of establishing experimental treatment centers in New Hampshire and the oversight thereof.

HB 1734-FN - AS AMENDED BY THE ~~SENATE~~HOUSE 11Mar2026...

Health, Human Services and Elderly Affairs

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.

0666h ~~05/14/2026 1864s~~ 26-2801 05/06 STATE OF NEW HAMPSHIRE In the Year of Our Lord Two Thousand Twenty-Six AN ACT ~~establishing~~authorizing ~~a committee to study the feasibility~~establishment of ~~establishing~~ experimental treatment centers~~centers. in New Hampshire and the oversight thereof.~~

~~There is an act established shall be committee known to as study the feasibility "John of Lewicke~~
~~establishing and experimental Michael treatment Yakubovich centers Experimental in Treatment New Centers~~
~~Hampshire Act". and the oversight thereof.~~

Experimental Treatment Centers.

CHAPTER 126-ZZ EXPERIMENTAL TREATMENT CENTERS 126-ZZ:1 Statement of Intent.

126-ZZ:2 Definitions.

The "Eligible members~~patient~~" ~~of~~ means the a committee person shall to be ~~whom as all follows~~ of the following
apply:

(b) ~~Three~~The members~~physician of~~certifies the~~house~~writing of~~that representatives,~~they appointed~~have~~
~~by~~provided~~the speaker~~recommendation of~~and that the house~~patient of~~has representatives,~~considered
~~one~~alternative~~of~~treatments~~whom~~approved~~shall~~be a member of the minority~~FDA; party.~~

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

(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.

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"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.

~~Members Nothing of in the this committee chapter shall requires receive a mileage health at care the insurer legislative or rate any when state attending agency to the provide duties coverage off for the any committee experimental treatment.~~

~~HB 1734-FN - AS AMENDED BY THE HOUSE - Page 3 Duties-- III.~~

~~The Nothing committee in shall:~~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.

~~Determine~~Notwithstanding ~~what~~any ~~would~~provision ~~be~~of ~~needed~~law ~~for~~to ~~sufficient~~the ~~oversight~~contrary, the board of ~~experimental~~medicine ~~treatment~~shall ~~centers~~not ~~by~~revoke, the~~fail~~ department~~to~~ of~~renew~~, health~~or~~ and~~take~~ human~~any~~ services,~~other~~ the~~action~~ bureau~~against~~ of~~a~~ consumer~~physician's~~ protection~~license~~ at~~issued~~ the~~pursuant~~ department~~to~~ of~~RSA~~ justice, 329, and~~or~~ the~~any~~ office~~other~~ of~~law~~, professional~~based~~ licensure~~primarily~~ and~~on~~ certification,~~a~~ physician's recommendation to an eligible patient regarding or prescription for treatment under this chapter.

~~Solicit~~Notwithstanding ~~information~~any ~~and~~provision ~~testimony~~from the ~~department~~of health~~law~~ and~~to~~ human~~the~~ services,~~contrary~~, the ~~bureau~~department of consumer~~health~~ protection,~~and~~ the~~human~~ office~~services~~ of~~shall~~ profession~~not~~ licensure~~take~~ and~~action~~ certification~~against~~ on~~a~~ what~~provider~~ they~~licensed~~ would~~under~~ require~~RSA~~ in~~151~~, terms~~or~~ of~~any~~ legislation,~~other~~ rules,~~law~~, appropriation,~~based~~ and~~primarily~~ any~~on~~ potential~~the~~ federal~~institution's~~ waivers~~participation~~ to~~in~~ properly~~treatment~~ oversee~~authorized~~ these~~under~~ centers.~~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.

~~Solicit~~To ~~information~~obtain ~~and~~authorization ~~testimony~~from the ~~current~~department, ~~operator~~applicant~~s~~ of~~shall~~ an~~have~~ experimental~~a~~ treatment~~medical~~ center~~director~~ or~~who~~ is ~~a~~ trade~~physician~~ group~~licensed~~ representing~~to~~ experimental~~practice~~ treatment~~medicine~~ centers.~~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.

~~Solicit~~Authorized ~~information~~providers ~~and~~may ~~testimony~~administer ~~from~~experimental ~~a~~treatments ~~governmental~~to ~~oversight~~eligible body~~patients~~ from~~pursuant~~ another~~to~~ state~~RSA~~ that~~126-ZZ:2~~, currently~~II~~ allows~~if~~ experimental~~reviewed~~ treatment~~and~~ centers.~~approved~~ by a scientific review board established under this chapter.

The scientific review board shall determine the appropriate quality standards, HB 1734-FN - AS AMENDED BY THE HOUSE - Page 4 - 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.

~~Solicit~~Notwithstanding ~~information~~any ~~and~~law ~~testimony~~or ~~from~~regulation ~~anto~~ individual~~the~~ or~~contrary~~, entity~~health~~ with~~care~~ expertise~~facilities~~ in~~currently~~ the~~licensed~~ FDA~~under~~ drug~~RSA~~ and~~151~~ device~~may~~ approval~~add~~ process.~~experimental~~ treatment center services by obtaining authorization under this section without otherwise obtaining additional licensing.

~~Solicit~~Notwithstanding ~~information~~any ~~and~~law ~~testimony~~or ~~from~~regulation ~~anto~~ individual~~the~~ or~~contrary~~, entity~~authorized~~ experimental treatment centers may establish payment arrangements with ~~expertise~~patients, ~~in~~including ~~current~~direct ~~Good~~pay, ~~Manufacturing~~subscription ~~Practice~~models, (~~cGMP~~)membership ~~for~~fees, ~~drug~~or ~~manufacturing~~other payment structures, including digital currencies, with or without regard to insurance coverage requirements.

~~Research~~Notwithstanding ~~experimental~~any ~~treatment~~law ~~centers~~or ~~in~~regulation ~~other~~to ~~states~~,the ~~including~~contrary, all~~services~~ benefits~~provided~~ and~~by~~ consequences~~authorized~~ of~~experimental~~ the~~set~~treatment centers ~~in~~under ~~these~~this ~~states~~,chapter ~~including~~are patient~~exempt~~ outcomes~~from~~ and~~any~~ costs~~state~~ to~~insurance~~ the~~coverage~~ state's~~mandates~~, health~~network~~ care~~adequacy~~ system~~requirements~~, and prior authorization procedures.

~~HB 1734-FN - AS AMENDED BY THE SENATE - Page 2 - VIII.~~

~~Research~~The ~~the~~commissioner ~~feasibility~~may ~~of~~adopt ~~proper~~rules ~~oversight~~under ~~of~~RSA ~~these~~541-A ~~facilities~~,establishing ~~including~~minimum ~~oversight~~standards ~~challenges~~for ~~in~~scientific ~~other~~review ~~states~~boards, ~~that~~adverse ~~have~~event ~~implemented~~reporting, ~~these~~and ~~experimental~~authorization ~~treatment~~procedures.~~centers.~~

4IX. Chairperson;

Quorum. 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.

~~The X. members of the study committee shall elect a chairperson from among the members.~~

The first commissioner meeting may also enter into reciprocal agreements called with by other the states first-named or senate their member, similar agencies for cross-border treatment coordination and shared scientific review board recognition.

The first department meetings shall of issue the experimental committee treatment shall center be licenses held to within applicants 45 already days licensed of under another state's substantially similar law, provided the effective applicant date satisfies of paragraph this IV section, in New Hampshire.

Four A members state's of law is presumptively "substantially similar" to New Hampshire's if it provides for the committee licensure shall of constitute experimental at treatment quorum centers requiring approval of treatment protocols and assessment of experimental treatment for patient safety by scientific review boards.

5126-ZZ:6 Report. Manufacturing I.

The Authorized committee experimental shall treatment report centers its may findings manufacture and drugs, any biologics, recommendations or for devices proposed on-site legislation or to through the contracted president facilities, of provided the senate, center's the scientific speaker review of board the approves house of representatives, the senate manufacturing clerk, protocol the and house determines clerk, it the meets governor, quality and standards the equivalent state to library recognized on pharmaceutical or manufacturing before frameworks November for 1, patient 2026, safety.

6 The Effective scientific Date, review board shall determine the appropriate quality framework for manufacturing and compounding under this chapter for purposes of clinical use in experimental treatment centers.

This HB act 1734-FN shall take AS effect AMENDED upon BY its THE passage, HOUSE - Page 5 - II.

LBA The 26-2801 scientific 05/21/2026 review HB board 1734-FN shall FISCAL document NOTE its AS rationale AMENDED for BY approving THE manufacturing SENATE facilities (AMENDMENT and #2026-1864s) protocols, AN including ACT comparison establishing a committee to study recognized the industry feasibility standards of such establishing as experimental good treatment manufacturing centers practice in or New international Hampshire organization and for the standardization oversight frameworks, thereof.

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.

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:

HB 1734-FN - AS AMENDED BY THE HOUSE - Page 6 - (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.

LBA 26-2801 Revised 05/01/2026 HB 1734-FN- FISCAL NOTE AS AMENDED BY THE HOUSE (AMENDMENT #2026-0666h) AN ACT authorizing the establishment of experimental treatment centers.

~~The~~This Office of Legislative Budget Assistant states this bill ~~has~~does ~~not~~not ~~fiscal~~provide impactfunding, ~~on~~nor ~~state~~,does ~~county~~it ~~and~~authorize ~~local~~new expenditurespositions. ~~of revenue~~.

Estimated State Impact FY 2026 FY 2027 FY 2028 FY 2029 Revenue \$0 Indeterminable Indeterminable Indeterminable Revenue Fund(s) General fund Expenditures* \$0 \$2.5 million+ \$1 million+ \$1 million+ Funding Source(s) General fund Appropriations* \$0 \$0 \$0 \$0 Funding Source(s) 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 reassessed 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.

~~None~~ Department of Health and Human Services