HB 1292-FN - AS INTRODUCED

2026 SESSION

26-2819
05/07

HOUSE BILL ***1292-FN***

AN ACT expanding the right to try act to include certain qualifying severe illness and permitting certain regenerative stem cell therapies under the act.

SPONSORS: Rep. Layon, Rock. 13; Rep. D. McGuire, Merr. 14; Rep. Popovici-Muller, Rock. 17; Rep. Sabourin dit Choiniere, Rock. 30; Rep. Mary Murphy, Hills. 27; Rep. DeVito, Rock. 8; Rep. Polozov, Merr. 10; Rep. Aures, Merr. 13; Sen. Murphy, Dist 16; Sen. Sullivan, Dist 18

COMMITTEE: Judiciary

ANALYSIS

This bill:

I. Extends the right to try act to include patients with "qualifying severe illness" and defines related terms.

II. Removes the definition of "investigational drug, biologic, or device."

III. Permits access to unapproved treatments under specified conditions and adds a new section regulating regenerative stem cell therapies, including consent, accreditation, advertising, and disclosure requirements.

IV. Authorizes injunctive relief for violations and prohibits the use of stem cells derived from a fetus or embryo after an abortion.

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Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

26-2819
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STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Twenty-Six

AN ACT expanding the right to try act to include certain qualifying severe illness and permitting certain regenerative stem cell therapies under the act.

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

1 Legislative Findings and Purpose. The general court recognizes the significant potential of stem cell therapies in advancing medical treatments and improving patient outcomes and further recognizes the need to ensure that such therapies are provided using stem cells obtained in an ethical manner. It is the intent of the general court to foster medical innovation while upholding ethical standards that respect the sanctity of life. By encouraging the use of stem cell sources such as adult stem cells, umbilical cord blood, and other ethically obtained human cells, tissues, or cellular or tissue-based products, the state will advance regenerative medicine in a manner consistent with the values of this state.

2 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-b. "Human cells, tissues, or cellular or tissue-based products" means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. The term does not include:

(a) Vascularized human organs for transplantation;

(b) Whole blood or blood components or blood derivative products;

(c) Secreted or extracted human products, such as milk, collagen, and cell factors, other than semen;

(d) Minimally manipulated bone marrow for homologous use and not combined with another article other than water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow;

(e) Ancillary products used in the manufacture of human cells, tissues, or cellular or tissue-based products;

(f) Cells, tissues, and organs derived from animals other than humans;

(g) In vitro diagnostic products; or

(h) Blood vessels recovered with an organ which are intended for use in organ transplantation and labeled "For use in organ transplantation only."

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.~~] ***"Minimally manipulated" means:***

(a) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.

(b) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

II-a. "Other protected access" includes:

(a) "Expanded access" whereby the treating physician requests access to [~~an investigational~~] ***a*** 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. "Qualifying severe illness" means an illness that is both chronic and debilitating. A qualifying severe illness shall include any condition treated with stem cell therapy pursuant to the requirements of RSA 126-Z:9.

III-b. "Chronic and debilitating" shall have the same meaning as "severely debilitating" as defined under 21 CFR section 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.

IV-a. "Stem cell therapy" means a treatment involving the use of afterbirth placental perinatal stem cells, or human cells, tissues, or cellular or tissue-based products, which complies with the regulatory requirements provided in this section. The term does not include treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion.

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 FDA available to patients if the manufacturer and patient satisfy the requirements of RSA 126-Z:3, II. 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 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.

3 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.

4 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.

5 New Section; Regenerative Stem Cell Therapies. Amend RSA 126-Z by inserting after section 8 the following new section:

126-Z:9 Regenerative Stem Cell Therapies.

I. A physician may perform stem cell therapy that is not approved by the United States Food and Drug Administration if such therapy is used for treatment or procedures addressing disease states that are within the scope of practice for such physician and the therapies are related to orthopedics, wound care, or pain management.

II. To ensure that the retrieval, manufacture, storage, and use of stem cells used for therapies conducted under this section meet the highest standards, any stem cells used by a physician for therapy provided under this section shall:

(a) Be retrieved, manufactured, and stored in a facility that is registered and regulated by the United States Food and Drug Administration;

(b) Be retrieved, manufactured, and stored in a facility that is certified or accredited by one of the following entities:

(1) National Marrow Donor Program;

(2) World Marrow Donor Association;

(3) Association for the Advancement of Blood and Biotherapies; or

(4) American Association of Tissue Banks;

(c) Contain viable or live cells upon post-thaw analysis and be included in a post-thaw viability analysis report for the product lot which shall be sent to the physician before use with the physician's patient; and

(d) The stem cells were obtained consensually. Stem cells are obtained consensually for the purposes of this provision if the stem cells comply with II(b) or if consent was given as listed below:

(1) If the stem cells were from a placenta or foreskin, by the parents of the child who produced the stem cells, either on a form provided as part of prenatal care or at the hospital during the birthing visit;

(2) If the stem cells are obtained from a minor child after the neonatal period, by a parent or from the child's legal guardian; or

(3) If the stem cells are obtained from an adult, by the adult.

III. A physician performing stem cell therapy shall not obtain stem cells for therapies from a facility engaging in the retrieval, manufacture, or storage of stem cells intended for human use under this section unless the facility maintains valid certification or accreditation as required by this subsection. Any contract or other agreement by which a physician obtains stem cells for therapies from such a facility shall include the following:

(a) A requirement that the facility provide all of the following information to the physician:

(1) The name and address of the facility;

(2) The certifying or accrediting organization;

(3) The type and scope of certification or accreditation;

(4) The effective and expiration dates of the certification or accreditation; and

(5) Any limitations or conditions imposed by the certifying or accrediting organization.

(b) A requirement that the facility notify the physician within 30 days after any change in certification or accreditation status, including renewal, suspension, revocation, or expiration.

IV.(a) A physician who conducts stem cell therapy pursuant to this section shall include the following in any form of advertisement:

THIS NOTICE MUST BE PROVIDED TO YOU UNDER NEW HAMPSHIRE LAW. This physician performs one or more stem cell therapies that have not yet been approved by the United States Food

and Drug Administration. You are encouraged to consult with your primary care provider before undergoing any stem cell therapy.

(b) The notice required under subparagraph (a) shall be clearly legible and in a type size no smaller than the largest type size used in the body text of the advertisement.

V.(a) A physician who conducts stem cell therapy pursuant to this section shall obtain a signed consent form from the patient before performing the stem cell therapy.

(b) The consent form shall be signed by the patient or, if the patient is not legally competent, the patient's representative, and shall state all of the following in language the patient or his or her representative may reasonably be expected to understand:

(1) The nature and character of the proposed treatment;

(2) That the proposed stem cell therapy has not yet been approved by the United States Food and Drug Administration;

(3) The anticipated results of the proposed treatment;

(4) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including non-treatment; and

(5) That the patient is encouraged to consult with his or her primary care provider before undergoing any stem cell therapy.

VI. This section shall not apply to the following:

(a) A physician who has obtained approval for an investigational new drug or device from the United States Food and Drug Administration for the use of human cells, tissues, or cellular or tissue-based products; or

(b) A physician who performs stem cell therapy under an employment or other contract on behalf of an institution certified or accredited by any of the following:

(1) The Foundation for the Accreditation of Cellular Therapy;

(2) The Blood and Marrow Transplant Clinical Trials Network;

(3) The Association for the Advancement of Blood and Biotherapies; or

(4) An entity with expertise in stem cell therapy as determined by the department.

VII. A violation of this section may subject the physician to disciplinary action by the board of medicine.

VIII. A physician shall be guilty of a class B felony and subject to disciplinary action under this section for willfully performing or actively participating in treatment or research using human cells or tissues derived from a fetus or an embryo after an abortion.

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

LBA
26-2819
10/29/25

HB 1292-FN- FISCAL NOTE
AS INTRODUCED

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FISCAL IMPACT:

Estimated State Impact				
	FY 2026	**FY 2027**	**FY 2028**	**FY 2029**
Revenue	$0	$0	$0	$0
Revenue Fund	None			
Expenditures*	Indeterminable			
Funding Source	General Fund			
Appropriations*	$0	$0	$0	$0
Funding Source	None			

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

Estimated Political Subdivision Impact				
	FY 2026	**FY 2027**	**FY 2028**	**FY 2029**
County Revenue	$0	$0	$0	$0
County Expenditures	Indeterminable			
Local Revenue	$0	$0	$0	$0
Local Expenditures	Indeterminable			

METHODOLOGY:

This bill adds, deletes, or modifies a criminal penalty, or changes statute to which there is a penalty for violation. Therefore, this bill may have an impact on the judicial and correctional systems, which could affect prosecution, incarceration, probation, and parole costs, for the state, as well as county and local governments. A summary of such costs can be found at: https://gencourt.state.nh.us/lba/Budget/Fiscal_Notes/JudicialCorrectionalCosts.pdf

AGENCIES CONTACTED:

Judicial Branch, Judicial Council, Department of Justice, Department of Corrections, New Hampshire Association of Counties, and New Hampshire Municipal Association