

SB 504 - AS AMENDED BY THE HOUSE

03/26/2026 1225s
03/26/2026 1262s
14May2026... 1742h
14May2026... 1951h

2026 SESSION

26-2100
09/05

SENATE BILL **504**

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.

SPONSORS: Sen. Rochefort, Dist 1; Sen. Pearl, Dist 17; Rep. C. McGuire, Merr. 27

COMMITTEE: Health and Human Services

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.

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

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Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

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STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Twenty-Six

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.

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

1 1 New Paragraph; Controlled Drug Act; Dealing In or Possessing Prescription Drugs. Amend
2 RSA 318:42 by inserting after paragraph VII-b the following new paragraph:

3 VII-c. The dispensing of up to a 30-day supply of noncontrolled oral anti-cancer medication
4 by a licensed health care professional legally authorized to prescribe and administer medications to a
5 patient under a provider's care or supervision so long as the following criteria are met:

6 (a) The dispensing clinic maintains on staff a full-time licensed pharmacist who is
7 available for consultation with the prescribing provider and the patient.

8 (b) In-office dispensing is conducted in a way consistent with United States
9 Pharmacopeia standards as well as all relevant state and federal laws or rules.

10 2 Pharmacists and Pharmacies; Display of Licenses. Amend RSA 318:28 to read as follows:

11 318:28 ~~[Display]~~ **Availability** of Licenses. All licenses as pharmacists shall ~~[at all times be~~
12 ~~conspicuously displayed]~~ **be readily retrievable** in the pharmacy where the licensee is engaged as
13 such.

14 3 Pharmacists and Pharmacies; Licensure of Pharmacies. Amend RSA 318:39 to read as
15 follows:

16 318:39 Application; Display. Application for a permit shall be made in such manner and in such
17 form as the board may determine. The permit shall at all times be ~~[exposed in a conspicuous place]~~
18 **posted** in the pharmacy for which it is issued.

19 4 Pharmacists and Pharmacies; Licensed Pharmacists; Remote Processing. Amend RSA 318:15-
20 d, I to read as follows:

21 I. New Hampshire licensed pharmacists, **licensed advanced pharmacy technicians**,
22 certified New Hampshire pharmacy technicians, or registered New Hampshire pharmacy interns
23 may engage in remote processing, provided that all work requiring pharmacist supervision is
24 supervised by a licensed pharmacist through electronic or other remote means.

25 5 Controlled Drug Act; Labels. Amend RSA 318-B:13, II to read as follows:

26 II. Whenever a pharmacist dispenses any controlled drug on prescription issued by a
27 practitioner, he or she shall affix to the container in which such drug is dispensed a label showing

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1 the name, address, and registry number of the pharmacy [~~and name or the initials of the~~
2 ~~pharmacist~~]; the name of the prescribing practitioner; the prescription identification number; the
3 name of the patient; the date dispensed; any directions as may be stated on the prescription; and the
4 name and strength and quantity of the drug dispensed. All drugs dispensed to a patient that have
5 been filled using a centralized prescription processing system shall bear a label containing an
6 identifiable code that provides a complete audit trail of the dispensing of the drug and
7 pharmaceutical care activities. No person shall alter, deface, or remove any label so affixed.

8 6 Pharmacists and Pharmacies; Definitions; Practice of Pharmacy. RSA 318:1, XIV is repealed
9 and reenacted to read as follows:

10 XIV.(a) "Practice of pharmacy" means the scope of practice for the provision of patient care
11 services by a pharmacist shall be based on their education, training, and experience, and determined
12 by practice setting and in accordance with generally accepted standards of care, including but not
13 limited to:

- 14 (1) The interpretation and evaluation of prescription orders;
- 15 (2) The compounding, dispensing, labeling, administering, and distribution of drugs
16 and devices;
- 17 (3) The selection, evaluation, and monitoring of drug and drug-related therapies;
- 18 (4) The performance of drug utilization reviews and medication therapy
19 management;
- 20 (5) The participation in collaborative pharmacy practice and collaborative pharmacy
21 practice agreements as defined in RSA 318:1, XXVI - XXVII, and RSA 318:16-a;
- 22 (6) The prescribing, ordering, administering, and interpretation of laboratory tests,
23 controlled and noncontrolled drugs, and devices in accordance with applicable state and federal law;
- 24 (7) The education and counseling of patients and health care professionals on the
25 therapeutic use, potential hazards, and outcomes of drugs and devices;
- 26 (8) The maintenance of appropriate records and the safe storage and handling of
27 drugs and devices;
- 28 (9) The interprofessional communication with appropriate health care providers to
29 ensure continuity of care;
- 30 (10) Any other professional acts, services, operations, or transactions necessary to
31 the operation and management of pharmacy practice.

32 (b) Nothing in this paragraph shall be construed to limit or restrict the provision of
33 patient care services by pharmacists otherwise authorized under federal or state law or regulations,
34 including those performed pursuant to protocol, collaborative practice agreements, or standing
35 orders.

36 (c) Nothing in this paragraph shall be interpreted to permit an alteration of a
37 prescribing clinician's diagnosis.

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1 7 Pharmacy Board; Rulemaking Authority. Amend RSA 318:5-a, XVII to read as follows:

2 XVII. The education and training standards and other requirements for pharmacists who,
3 pursuant to prescriber-approved protocol,[-

4 ~~(a)]~~ administer prescription medications ***outside the parameters of a collaborative***
5 ***pharmacy practice agreement***, including influenza immunizations.

6 ~~[(b) Engage in collaborative pharmacy practices.]~~

7 8 Licensed Pharmacists; Standards for Collaborative Pharmacy Practice. Amend RSA 318:16-a,
8 I(c) to read as follows:

9 (c) Have the knowledge base necessary for proper monitoring, including, but not limited
10 to, associated disease states, relevant laboratory tests, adverse events, drug and food interactions,
11 safety, and efficacy. ~~[Depending upon the complexity of the services being provided, the pharmacist~~
12 ~~may be required to have additional credentials or training and shall demonstrate the receipt of~~
13 ~~approval by the board of pharmacy.]~~

14 9 Pharmacy Board; Rulemaking; Examinations. Amend RSA 318:5-a, IV(a) to read as follows:

15 (a) The subjects to be tested ***pursuant to RSA 318:19;***

16 10 Pharmacy Board; Rulemaking; Licensed Advanced Pharmacy Technicians. Amend RSA
17 318:5-a, XI-c(a) to read as follows:

18 (a) Requirements for licensure, including experience and education requirements. ***Any***
19 ***examination requirement for licensure shall be limited to the scope of practice, and such***
20 ***requirement shall be suspended if the board is unable to verify that the exam complies with***
21 ***board requirements.***

22 11 Pharmacists and Pharmacies; Examinations. Amend RSA 318:19 to read as follows:

23 318:19 Examinations. – Applicants for licensure as pharmacists shall, to prove their respective
24 requisite knowledge, be examined to a properly varying degree in pharmacy-related subject areas
25 which may include chemistry, math, pharmacology, pharmacy theory, the practice of pharmacy ~~[and~~
26 ~~pharmacy law]~~, and any other areas as the board may prescribe, ***except that the board shall not***
27 ***require any applicant to be examined on pharmacy state-specific or universal state level***
28 ***jurisprudence or law.***

29 12 Pharmacy Board; Enforcement of Law. Amend RSA 318:8 to read as follows:

30 318:8 Enforcement of Law.

31 ***I.*** It shall be the duty of the board, through officials and employees appointed by it or under
32 its supervision for that purpose, and of all peace officers within the state, and of all county attorneys,
33 to enforce all the provisions of this chapter. When so requested, the department of health and
34 human services and its officials and employees shall cooperate with the board in collecting and
35 analyzing samples of drugs and medicines sold, or suspected of being sold, in violation of this
36 chapter. The members of the board, its inspectors and investigators shall have free access during

1 business hours to all places where drugs, medicines, poisons or hypodermic devices are held, stored,
2 or offered for sale and to all records of sale and disposition of drugs.

3 ***II. It shall also be the duty of the board, through officials and employees appointed***
4 ***by it or under its supervision for that purpose, to evaluate whether a specific act is within***
5 ***the practice of pharmacy, or whether an act can be delegated to other individuals under***
6 ***pharmacist supervision. A licensee or registrant of the board of pharmacy shall***
7 ***independently determine whether:***

8 ***(a) The act is expressly prohibited by:***

9 ***(1) This chapter;***

10 ***(2) The controlled drug act, RSA 318-B;***

11 ***(3) The rules of the board of pharmacy; or***

12 ***(4) Any other applicable state or federal laws or regulations;***

13 ***(b) The act is consistent with the individual's education, training, and***
14 ***experience; and***

15 ***(c) Performance of the act is within the accepted standard of care that would be***
16 ***provided in a similar setting by a reasonable and prudent individual with similar***
17 ***education, training, and experience.***

18 13 Pharmacist Administration of Vaccines. Amend RSA 318:16-b, II to read as follows:

19 II. A pharmacist, pharmacy intern, [or] licensed advanced pharmacy technician, ***or***
20 ***certified pharmacy technician***, under the supervision of an on-site immunizing pharmacist may
21 administer vaccines licensed by the United States Food and Drug Administration [~~that are~~
22 ~~recommended by the United States Centers for Disease Control and Prevention Advisory Committee~~
23 ~~on Immunization Practices, or successor organization,~~] to individuals 18 years of age or older as
24 ordered by an immunizing pharmacist.

25 14 Short Title. Sections 14 through 16 of this act shall be known as the "John Lewicke and
26 Michael Yakubovich Experimental Treatment Centers Act".

27 15 New Chapter; Experimental Treatment Centers. Amend RSA by inserting after chapter 126-
28 Z the following new chapter:

29 CHAPTER 126-ZZ

30 EXPERIMENTAL TREATMENT CENTERS

31 126-ZZ:1 Statement of Intent.

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

37 126-ZZ:2 Definitions.

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1 In this chapter:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

32 IV. “Other protected access” includes expanded access or compassionate use, in which the
33 treating physician has requested access under 21 C.F.R. Part 312, Subpart I and other applicable
34 FDA regulations or off-label use consistent with the physician’s professional obligations under RSA
35 329.

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

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

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

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

8 126-ZZ:3 Availability of Investigational Drugs, Biologics, or Devices.

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

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

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

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

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

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

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

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

34 126-ZZ:4 Limitation on State or Political Subdivision Action.

35 I. Notwithstanding any provision of law to the contrary, the board of medicine shall not
36 revoke, fail to renew, or take any other action against a physician's license issued pursuant to RSA

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1 329, or any other law, based primarily on a physician's recommendation to an eligible patient
2 regarding or prescription for treatment under this chapter.

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

6 126-ZZ:5 Experimental Treatment Center Licensing.

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

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

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

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

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

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

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

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

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

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

11 126-ZZ:6 Manufacturing

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

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

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

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

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

28 126-ZZ:7 Free Care and Public Benefits.

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

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

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

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

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

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

14 16 New Subparagraph; Health Care Facility Licensing; Exemptions; Experimental Treatment
15 Center. Amend RSA 151:2, II as follows by inserting after subparagraph (i) the following new
16 subparagraph:

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

21 17 Right to Try Act. Amend RSA 126-Z:1 through 126-Z:4 to read as follows:

22 126-Z:1 Definitions. In this chapter:

23 I. "Eligible facility" means a licensed New Hampshire institution that is operating under a
24 Federalwide Assurance ("FWA") for the Protection of Human Subjects under 42 U.S.C. section 289(a)
25 and 45 C.F.R. part 46. Any eligible facility is subject to the FWA laws, regulations, policies, and
26 guidelines including renewals or updates.

27 I-a. [~~Eligible patient" means a person to whom all of the following apply:~~

28 ~~(a) The person has been diagnosed with a terminal illness by the person's physician.~~

29 ~~(b) The person has already tried or is not a candidate for eligible United States Food and
30 Drug Administration (FDA) approved treatment options for their disease or condition.~~

31 ~~(c) The person is unable to participate in a clinical trial involving the eligible
32 investigational drug, biologic or device.~~

33 ~~(d) The person has given written informed consent for the use of the investigational
34 drug, biological product, or device or, if the patient is a minor or lacks the mental capacity to provide
35 informed consent, a parent or legal guardian has given written informed consent on the patient's
36 behalf.~~

1 ~~(e) The physician providing access to an investigational drug, biologic, or device will not~~
2 ~~be compensated directly by the manufacturer for providing access to this therapy.~~

3 I-b.] "Health care provider" means a physician licensed to practice medicine in the state of
4 New Hampshire.

5 [I-e.] **I-b.** "Individualized investigational treatment" means drugs, biologics, or devices
6 unique to and produced exclusively for use for an individual patient, based on their own genetic
7 profile, including but not limited to individualized gene therapy antisense oligonucleotides (ASO),
8 individualized neoantigen vaccines, and any other individualized treatment.

9 II. [~~Investigational drug, biologic, or device" means a drug, biologic, or device that has~~
10 ~~successfully completed phase one of a clinical trial, but has not been approved for general use by the~~
11 ~~FDA and remains under investigation in a clinical trial.~~

12 H-a.] "Other protected access" includes:

13 (a) "Expanded access" whereby the treating physician requests access to an
14 investigational drug, biologic, or device from the FDA and is subject to oversight from an
15 Institutional Review Board; and

16 (b) "Off-label use" means prescribing an FDA approved drug, biologic, or device for a use
17 not approved for that specific indication consistent with RSA 329:17, VI-b.

18 III. "Physician" means the licensed allopathic or osteopathic physician who is providing
19 medical care or treatment to the[eligible] patient for the terminal **or qualifying severe** illness.

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

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

24 IV. "Remote signing" means the signing of any form, witnessed by a notary public or a
25 licensed health care provider, providing written informed consent for a person diagnosed by a
26 physician with a terminal **or qualifying severe** illness to participate in a clinical trial or receive a
27 drug, biologic, or device, by the patient or, if the patient is a minor or lacks the mental capacity to
28 provide consent, by a parent or legal guardian on the patient's behalf.

29 V. "Telehealth prescreening" means any remote, real-time discussion intended, in part, to
30 determine whether a person with a terminal **or qualifying severe** illness may be:

31 (a) Ineligible for or not selected to participate in a clinical trial; or

32 (b) Ineligible to receive or not be offered a drug, biologic, or device.

33 VI. "Terminal illness" means diseases or conditions where the likelihood of death is high
34 unless the course of the disease is interrupted, and diseases or conditions with potentially fatal
35 outcomes, where the endpoint of a clinical trial analysis is survival, which is the definition of "life
36 threatening" under 21 C.F.R. section 312.81.

37 126-Z:2 Availability of Investigational Drugs, Biologics, or Devices; Costs; Coverage.

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

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

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

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

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

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

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

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

20 126-Z:3 Liability of Physician; Facility.

21 I. Notwithstanding any provision of law to the contrary, the board of medicine shall not
22 revoke, fail to renew, or take any other action against a physician's license issued pursuant to RSA
23 329 based primarily on a physician's recommendation to [~~an eligible~~] **a** patient regarding or
24 prescription for or treatment with [~~an investigational~~] **a** drug, biologic, or device **pursuant to this**
25 **chapter.**

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

30 III. Notwithstanding any provision of law to the contrary, a manufacturer of a drug, biologic,
31 or device, a pharmacist, a health care facility, a health care provider, or a person or entity involved
32 in the care of a patient using a drug, biologic, or device is immune from suit for any harm done to a
33 patient resulting from the drug, biologic, or device if:

34 (a) The person has a terminal **or qualifying severe** illness as determined by the
35 person's physician and a consulting physician;

1 (b) The person's physician has determined that the person has no comparable or
2 satisfactory United States Food and Drug Administration (FDA) approved treatment options
3 available not approved by the FDA to treat the disease or condition involved;

4 (c) The patient has given written informed consent for the use of the drug, biologic, or
5 device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent
6 or legal guardian has given written informed consent on the patient's behalf and, if the patient is a
7 legal adult, the consent is not contrary to the prior documented wishes of the patient;

8 (d) The manufacturer, pharmacist, facility, provider, or other person or entity has not
9 engaged in willful or reckless misconduct or other bad faith conduct. "Willful or reckless
10 misconduct" shall include, but is not limited to, any conduct intended to hasten the death of the
11 patient; and

12 (e) If the drug, biologic, or device is an individualized investigational treatment, it is
13 administered by a health care provider [at] *in cooperation with* an eligible facility.

14 126-Z:4 Private Cause of Action.

15 I. Nothing in this chapter shall be construed to create a private cause of action against any
16 person or entity except as specified in paragraph II.

17 II. Notwithstanding any provision of law to the contrary, any patient diagnosed with a
18 terminal *or qualifying severe* illness by a physician, and who has been treated, is being treated, or
19 otherwise could be treated in New Hampshire with a drug, biologic, or device, and is affected by a
20 violation of this chapter, or a health care facility or a health care provider involved in the treatment
21 of the patient, shall be entitled to petition the superior court for injunctive relief and reasonable
22 attorney's fees against any regulatory or law enforcement authority that violates this chapter.

23 18 Telehealth Prescreening. Amend RSA 126-Z:6, I to read as follows:

24 I. Notwithstanding any regulation or provision of law to the contrary, any health care
25 provider, while physically located in New Hampshire, may conduct a telehealth prescreening with
26 any patient, in any state or jurisdiction, who has been diagnosed by a physician with a terminal *or*
27 *qualifying severe* illness.

28 19 Statutory Construction. Amend RSA 126-Z:8 to read as follows:

29 126-Z:8 Statutory Construction. The general court enacts this chapter to promote maximum
30 access by removing barriers in state law and indemnifying those involved in providing potentially
31 life-saving *or dramatically life-improving* treatments and treatments to improve the quality of
32 patients' remaining life, to incentivize health care facilities, health care providers, manufacturers of
33 drugs, biologics and/or devices, and other persons and entities involved in the care of patients, to
34 treat terminal *and qualifying severe* illness, whether through company-sponsored clinical trial,
35 single-patient protocol, compassionate use protocol, or any other means of access to drugs, biologics,
36 and/or devices which gathers information on patient outcomes, and to make New Hampshire a
37 jurisdiction that attracts and fosters clinical trials and the development of drugs, biologics, and

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1 devices intended to treat terminal *and qualifying severe* illness. This chapter shall be construed
2 consistently with the general court's stated purpose.

3 20 Effective Date.

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

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

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