HB 446 - AS INTRODUCED

2015 SESSION

15-0242
01/05

HOUSE BILL ***446***

AN ACT relative to access to investigational drugs, biological products, and devices.

SPONSORS: Rep. Wright, Carr 8; Rep. Jones, Straf 24; Rep. Cheney, Straf 17; Rep. Hansen, Hills 22; Rep. Groen, Straf 10; Rep. Rideout, Coos 7; Rep. Beaudoin, Straf 9; Sen. Reagan, Dist 17

COMMITTEE: Judiciary

ANALYSIS

This bill establishes the Terminal Patient's Right to Try Act which allows a patient with a terminal illness access to investigational drugs, biological products, and devices.

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Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

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STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Fifteen

AN ACT relative to access to investigational drugs, biological products, and devices.

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

1 Statement of Intent; Findings.

I. The general court hereby finds and declares that:

(a) The process of approval for investigational drugs, biological products, and devices in the United States often takes many years.

(b) Patients who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States Food and Drug Administration (FDA).

(c) The standards of the FDA for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to terminally ill patients.

(d) Patients who have a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices.

(e) The use of available investigational drugs, biological products, and devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's physician and is not a decision to be made by the government.

II. Therefore, it is the intent of the general court to establish the Terminal Patients' Right-to-Try Act to allow terminally ill patients the option to try certain investigational drugs, products, and devices.

2 New Chapter; Terminal Patients' Right-to-Try Act. Amend RSA by inserting after chapter 126-Y the following new chapter:

CHAPTER 126-Z

TERMINAL PATIENTS' RIGHT TO TRY ACT

126-Z:1 Definitions. In this chapter:

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

(a) The person has a terminal 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 diagnose, monitor, or treat the disease or condition involved and that the probable risk to the person from the investigational drug, biological product, or device is not greater than the probable risk from the disease or condition.

(c) The person has received a prescription or recommendation from the person's physician for an investigational drug, biological product, 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 person has documentation from the person's physician that the person has met the requirements of this paragraph.

II. "Investigational drug, biological product, or device" means a drug, biological product, 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.

III. "Physician" means the licensed physician who is providing medical care or treatment to the eligible patient for the terminal illness. The term "physician" shall not include a primary care physician.

IV. "Terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

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

I. A manufacturer of an investigational drug, biological product, or device may make available an investigational drug, biological product, or device to eligible patients pursuant to this chapter. A manufacturer may:

(a) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(b) Require an eligible patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.

(c) Require an eligible patient to participate in data collection relating to the use of the investigational drug, biological product, 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, biological product, or device.

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 solely on a physician's recommendation to an eligible patient regarding or prescription for or treatment with an investigational drug, biological product, or device.

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 solely on the institution's participation in the treatment or use of an investigational drug, biological product, or device under this chapter.

126-Z:4 Severability. If any provision of this chapter, or the application thereof to any person or circumstance is held invalid, the invalidity does not affect the other provisions or applications of the chapter which can be given effect without the invalid provisions or applications and to this end the provisions of this chapter are severable.

3 Effective Date. This act shall take effect January 1, 2016.