SENATE, No. 2186

STATE OF NEW JERSEY

216th LEGISLATURE

INTRODUCED JUNE 16, 2014

Sponsored by:
Senator DIANE B. ALLEN
District 7 (Burlington)
Senator JOSEPH F. VITALE
District 19 (Middlesex)

Co-Sponsored by:
Senator Codey

SYNOPSIS

Establishes “Right to Try Act” permitting terminally ill patients to access investigational drugs and treatment.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 9/16/2014)

AN ACT concerning access to investigational health care treatment and supplementing Title 26 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. This act shall be known and may be cited as the "Right to Try Act."

2. The Legislature 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 are terminally ill 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.

c. The standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to patients who have a terminal illness.

d. Patients who are terminally ill have a fundamental right to attempt to pursue the preservation of their 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 in consultation with the patient's health care provider and is not a decision to be made by the government.

f. The decision to use an investigational drug, biological product, or device should be made with full awareness of the potential risks, benefits, and consequences to the patient and the patient's family.

g. It is the intent of the Legislature to allow patients who are terminally ill to use potentially life-saving investigational drugs, biological treatments, and devices.

3. As used in this act:

"Eligible patient" means a person who has:

(1) A terminal illness;

(2) Considered all other treatment options currently approved by the United States Food and Drug Administration in consultation with a physician licensed pursuant to Title 45 of the Revised Statutes;

(3) Received a prescription or recommendation by a physician for an investigational drug, biological product, or device;

(4) Given informed, written consent for the use of the investigational drug, biological product, or device. If the patient is a minor or lacks the mental capacity to provide informed consent, a

parent or legal guardian may provide informed, written consent on the patient's behalf; and

(5) Documentation from the physician indicating the person has met these requirements.

"Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial approved by the United States Food and Drug Administration, but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

"Terminal illness" means a medical condition that results in a patient's life expectancy being 12 months or less as determined by a physician.

4. a. A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients pursuant to this act. Nothing in this act shall be construed to require a manufacturer to make an investigational drug, biological product, or device available.

b. A manufacturer may:

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

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

5. A government medical assistance program or private health insurer may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device.

6. The State Board of Medical Examiners shall not revoke a license, fail to renew a license, or take any other disciplinary action under Title 45 of the Revised Statutes against a physician solely based on the physician's recommendation, prescription, or treatment of an eligible patient with an investigational drug, biological product, or device consistent with this act.

7. Any official, employee, or agent of a State or local government who attempts to block or who does block access of an eligible patient to an investigational drug, biological product, or device is a disorderly person.

8. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity shall not affect any other provision or application of the act which can be given effect

without the invalid provision or application, and to this end the provisions of this act are severable.

9. This act shall take effect immediately.

STATEMENT

This bill would permit patients who are terminally ill to access investigational drugs, biological products, and devices that have not yet been approved by the United States Food and Drug Administration (FDA).

To use an investigational drug, biological product, or device, the patient would be required to: have a medical condition that results in a life expectancy of less than 12 months; have consulted with a physician and considered all other treatment options currently approved by the FDA; have received a prescription or recommendation from a physician for the investigational drug, biological product, or device; and give informed, written consent to use of the investigational drug, biological product, or device. The physician would be required to document that the patient has met these requirements.

The bill would require that the investigational drug, biological product, or device has successfully completed phase one of an FDA-approved clinical trial and remains under investigation in an FDA-approved clinical trial. The manufacturer would be permitted to provide the investigational drug, biological product, or device without compensation or require the patient pay the costs associated with its manufacture. Government medical assistance programs and private health insurers would not be required to provide coverage for the cost of an investigational drug, biological product, or device, but private insurers would be permitted to provide coverage if they so choose.

The bill would prohibit the State Board of Medical Examiners from revoking a license, failing to renew a license, or taking any other disciplinary action against a physician solely based on the physician’s recommendation, prescription, or treatment of an eligible patient with an investigational drug, biological product, or device consistent with the provisions of the bill.

Any official, employee, or agent of a State or local government who attempts to block or who does block access of an eligible patient to an investigational drug, biological product, or device would be a disorderly person, which offense is punishable by imprisonment for up to six months, a $1,000 fine, or both.