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SENATE BILL NO. 732

Offered January 14, 2015

Prefiled December 15, 2014

A BILL to amend the Code of Virginia by adding in Chapter 34 of Title 54.1 an article numbered 4.1, consisting of sections numbered 54.1-3442.1 through 54.1-3442.4, relating to expanded access to investigational drugs.

Patrons—Stanley, Reeves and Stuart

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 34 of Title 54.1 an article numbered 4.1, consisting of sections numbered 54.1-3442.1 through 54.1-3442.4, as follows:

Article 4.1.

Expanded Access to Investigational Drugs, Biological Products, and Devices.

§ 54.1-3442.1. Definitions.

As used in this article, unless the context requires a different meaning:

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

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

§ 54.1-3442.2. Eligibility for expanded access to investigational drugs, biological products, and devices; written, informed consent to treatment.

A. A person shall be eligible for expanded access to investigational drugs, biological products, or devices if:

1. He has a terminal illness, attested to by his treating physician;

2. He has, in consultation with his treating physician, considered all other treatment options currently approved by the U.S. Food and Drug Administration;

3. He has been denied opportunity to participate in a clinical trial for the treatment of his terminal illness within one week of completion of the clinical trial application process or has been unable to participate in a clinical trial for the treatment of his terminal illness within 100 miles of his home address;

4. He has received a recommendation from his treating physician for use of an investigational drug, biological product, or device for treatment of his terminal illness; and

5. He has given informed consent in writing to use of the investigational drug, biological product, or device for treatment of his terminal illness or, if he is a minor or is otherwise incapable of providing informed consent, his parent or legal guardian has given informed consent in writing to use of the investigational drug, biological product, or device.

A person shall not be eligible for expanded access to investigational drugs, biological products, or devices if he is being treated as an inpatient in a licensed hospital.

B. Written informed consent to use of an investigational drug, biological product, or device shall include:

1. An explanation of the currently approved products and treatments for the person's terminal condition;

2. A statement that the person concurs with his treating physician in believing that all currently approved treatments are unlikely to prolong the person's life;

3. An explanation of the specific investigational drug, biological product, or device proposed for treatment of the person's terminal condition;

4. A description of the possible outcomes resulting from use of the investigational drug, biological product, or device to treat the person's terminal condition, including a description of the most likely outcome and a statement that new, unanticipated, different, or worse symptoms might result from and that death could be hastened by the proposed treatment, based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the person's condition;

5. A statement that the person may be required to pay any costs associated with use of the investigational drug, biological product, or device;

6. A statement that the person's eligibility for hospice care may be withdrawn if the patient begins

treatment of his terminal illness with an investigational drug, biological product, or device and that care may be reinstated if such treatment ends and the patient meets hospice eligibility requirements;

7. A statement that home health care may be denied if the person begins treatment of his terminal illness with an investigational drug, biological product, or device; and

8. A statement that the person or, if the person is a minor or lacks capacity to provide informed consent, his parent or legal guardian consents to the use of the investigational drug, biological product, or device for treatment of his terminal condition.

§ 54.1-3442.3. Expanded access to investigational drugs, biological products, or devices; cost; insurance coverage.

A. A manufacturer of an investigational drug, biological product, or device may make such investigational drug, biological product, or device available to a person who meets the criteria set forth in § 54.1-3442.2; however, nothing in this article shall require a manufacturer of an investigational drug, biological product, or device to make such investigational drug, biological product, or device available to such person.

B. A manufacturer that makes an investigational drug, biological product, or device available to a person who meets the criteria set forth in § 54.1-3442.2 may provide the investigational drug, biological product, or device to the person free of charge or may require the person to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device. If the person dies during treatment of his terminal illness with an investigational drug, biological product, or device, the person's heirs shall not be liable for any outstanding debt related to the cost of or costs associated with manufacture of the investigational drug, biological product, or device.

C. An insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporation providing individual or group accident and sickness subscription contracts; or health maintenance organization providing a health care plan for health care services may provide coverage for costs related to treatment of a person's terminal illness with an investigational drug, biological product, or device; however, nothing in this article shall require an insurer, corporation, or health maintenance organization proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporation providing individual or group accident and sickness subscription contracts; or health maintenance organization providing a health care plan for health care services to provide coverage for costs related to treatment of a person's terminal illness with an investigational drug, biological product, or device.

D. An insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporation providing individual or group accident and sickness subscription contracts; or health maintenance organization providing a health care plan for health care services may deny coverage to a person receiving treatment with an investigational drug, biological product, or device from the time the person begins use of the investigational drug, biological product, or device through a period not to exceed six months from the time the investigational drug, biological product, or device is no longer used by the person, except that coverage may not be denied for a preexisting condition or for benefits that commenced prior to the time treatment with the investigational drug, biological product, or device began.

E. An individual who prevents or attempts to prevent a manufacturer from making an investigational drug, biological product, or device available to a person in accordance with the provisions of this section is guilty of a Class 1 misdemeanor.

§ 54.1-3442.4. Recommendation not deemed unprofessional conduct.

No health care provider who recommends the use of an investigational drug, biological product, or device for treatment of a patient's terminal illness in accordance with subdivision 4 of § 54.1-3442.2 shall be deemed to have engaged in unprofessional conduct solely on the grounds of such recommendation.