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SENATE BILL NO. 732

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Education and Health on February 5, 2015)

(Patrons Prior to Substitute—Senators Stanley, Stuart [SB 1149], and Reeves [SB 1222])

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.

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.

"Treating physician" means an individual's physician who (i) is providing or has previously provided the individual with medical treatment or evaluation or (ii) has or previously had an ongoing treatment relationship with the individual.

§ 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 and the treating physician has determined that no reasonable opportunity exists for him to participate in an ongoing clinical trial for his terminal illness;

3. 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

4. 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 illness;

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; a corporation providing individual or group accident and sickness subscription contracts; or a 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 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; a corporation providing individual or group accident and sickness subscription contracts; or a 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.

§ 54.1-3442.4. Recommendation not deemed unprofessional conduct.

A. Notwithstanding any other provision of law to the contrary, a health care provider as defined in § 8.01-581.1 who recommends an investigational drug, biological product, or device to a person who meets the criteria set forth in § 54.1-3442.2 shall be immune from civil liability for any adverse action, condition, or other outcome resulting from the patient's use of the investigational drug, biological product, or device.

B. Notwithstanding any other provision of law to the contrary, a manufacturer, distributor, administrator, health care provider as defined in § 8.01-581.1, sponsor, or physician who manufactures, supplies, distributes, administers, prescribes, or recommends an investigational drug, biological product, or device to a person who meets the criteria set forth in § 54.1-3442.2 shall be immune from suit and liability caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescription, recommendation, administration, efficacy, or use of such investigational drug, biological product, or device made available to such person.

C. No claim or cause of action against a manufacturer, distributor, administrator, health care provider as defined in § 8.01-581.1, sponsor, or physician who manufactures, supplies, distributes, administers, prescribes, or recommends an investigational drug, biological product, or device to a person who meets the criteria set forth in § 54.1-3442.2 shall exist in any federal or state court for claims of property, personal injury, or death caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescription, recommendation, administration, efficacy, or use of such investigational drug, biological product, or device made available to such person.

D. No health care provider who recommends, prescribes, administers, distributes, or supplies an investigational drug, biological product, or device to a person who meets the criteria set forth in § 54.1-3442.2 shall be deemed to have engaged in unprofessional conduct, or shall be adversely affected in any decision relating to licensure, on such grounds.