VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act 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.

[S 732]

Approved

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.

"Terminal condition" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical probability, a patient cannot recover and (i) the patient's death is imminent or (ii) the patient is in a persistent vegetative state.

"Treating physician" means a physician who is providing or has previously provided medical treatment or evaluation to and has or previously had an ongoing treatment relationship with the person.

§ 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 condition, attested to by his treating physician and confirmed by a second physician not previously involved in the treatment of the person who has conducted an independent examination of the person;

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 condition;

3. The potential benefits of use of the investigational drug, biological product, or device to treat his terminal condition are greater than the potential risks of the use of the investigational drug, biological product, or device to treat his terminal condition;

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 condition; and

5. He or, if he is incapable of making an informed decision, his legally authorized representative has given written informed consent to use of the investigational drug, biological product, or device for treatment of his terminal condition or, if the person is a minor or lacks capacity to provide informed consent, his parent or legal guardian has given written informed consent to the use of the investigational drug, biological product, or device for treatment of his terminal condition.

Documentation indicating that the person meets the criteria for eligibility for expanded access to investigational drugs, biological products, or devices shall be provided by the person's treating physician and shall be included in the person's medical record.

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 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 the person to participate in an ongoing clinical trial for his terminal condition;

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 possible outcomes resulting from use of the investigational drug, biological

product, or device to treat the person's terminal condition, including a statement that new, unanticipated, different, or worse symptoms might result from and 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 terminal 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; and

6. 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 subsection A of § 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 subsection A of § 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.

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 condition 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 condition with an investigational drug, biological product, or device.

§ 54.1-3442.4. Limitation of liability.

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 subsection A of § 54.1-3442.2 shall be immune from civil liability for any adverse action, condition, or other outcome resulting from the person'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 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 as defined in § 8.01-581.1 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.

E. Nothing in this article shall require a person to violate or act in contravention of any federal or state law as such law relates to the prescribing, dispensing, administration, or use of an investigational drug, biological product, or device.