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HOUSE BILL NO. 2050

Offered January 14, 2015
Prefiled January 14, 2015

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—Sickles, Cole, Hope, Kory, Lindsey, McQuinn, Simon and Spruill

Referred to Committee on Health, Welfare and Institutions

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 an advanced stage of a disease with an unfavorable prognosis and no known cure.

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

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

1. He has a terminal condition;

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

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

4. He 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.

§ 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.

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

§ 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 3 of § 54.1-3442.2 shall be deemed to have engaged in unprofessional conduct solely on the grounds of such recommendation.