Department of Legislative Services

Maryland General Assembly
2024 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 676 (Delegate M. Morgan, *et al.*)
Health and Government Operations Finance

Right to Try Act - Individualized Investigational Treatments

This bill specifies that a manufacturer operating within an "eligible facility" may provide an "individualized investigational treatment" to an "eligible patient" without compensation or charge the patient for the cost of, or associated with, the manufacture of the treatment. A carrier, third-party administrator, or government agency may provide coverage for the cost of an individualized investigational treatment or related services. A government agency is not required to pay costs associated with the use, care, or treatment of an individual with an individualized investigational treatment, nor is a hospital or another health care facility required to provide new or additional services unless approved by the hospital or health care facility. The bill also (1) alters the definitions of "eligible patient" and "informed consent"; (2) repeals the definition of "investigational drug, biological product, or device" and replaces references to that term with "individualized investigational treatment"; (3) repeals restrictions on the receipt of payments from eligible patients and the prohibition on manufacturers profiting from the provision of an investigational drug, biological product, or device; and (4) makes conforming changes.

Fiscal Summary

State Effect: The bill is not anticipated to materially affect State operations or finances.

Local Effect: The bill does not materially affect local government operations or finances.

Small Business Effect: Minimal.

Analysis

Bill Summary/Current Law:

Federal Food, Drug, and Cosmetic Act

Section 505 of the federal Food, Drug, and Cosmetic Act prohibits the sale or distribution of a drug into interstate commerce until the drug is proven safe and effective. Under the U.S. Food and Drug Administration (FDA) Expanded Access Program, also referred to as "compassionate use," an investigational medical product (a drug, biologic, or medical device that has not received FDA approval) may be used outside of a clinical trial. Expanded access may be appropriate when all of the following apply: (1) a patient has a serious or immediately life-threatening disease or condition; (2) there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; (3) patient enrollment in a clinical trial is not possible; (4) potential patient benefit justifies the potential risks of treatment; and (5) providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

Trickett Wendler Right to Try Act of 2017

The federal Trickett Wendler Right to Try Act of 2017 allows an eligible patient (a patient who is terminally ill) to appeal directly to a drug manufacturer for access to an investigational drug that has completed a Phase I clinical trial and bypass FDA's Expanded Access Program. The Act also exempts a physician or drug company from liability for prescribing or providing an experimental drug, biological product, or device and prohibits a federal agency from using negative information, such as patient injury or death as a result of the use of an experimental drug, biological product, or device under a "right to try" act, to adversely impact the review or approval of the experimental drug, biological product, or device.

Maryland Right to Try Act

Chapter 771 of 2017 authorizes a manufacturer of an investigational drug, biological product, or device to provide the investigational drug, biological product, or device to an eligible patient. Chapter 771 specifies that a manufacturer may either provide the drug, biological product, or device without compensation or charge the patient, subject to specified limitations, for the cost of, or associated with, the manufacture of the specific drug, biological product, or device. During the time that the patient is taking or using the drug, biological product, or device, the manufacturer has a duty to inform the patient and their health care provider of any side effects or risks as required to be disclosed to FDA during a drug approval process.

Definitions

Under current law, an "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 yet been approved for general use by FDA and remains under investigation in an FDA-approved clinical trial.

The bill repeals this definition, as well as references to the term, which are replaced with the term "individualized investigational treatment." "Individualized investigational treatment" means a drug, biological product, or device that is unique to and produced exclusively for use by an individual based on the genetic profile of the individual. "Individualized investigational treatment" includes individualized gene therapy, antisense oligonucleotides, and individualized neoantigen vaccines.

Consistent with the bill's repeal of the term "investigational drug, biological product, or device" and its replacement with "individualized investigational treatment," the bill repeals the limitations on a manufacturer who elects to charge a patient for the costs of, or associated with, the manufacture of an investigational drug, biological product, or device, including the prohibition on a manufacturer profiting from providing an investigational drug, biological product, or device provided to an eligible patient. The bill also repeals the provision relating to a manufacturer's duty to inform the patient and their health care provider of any side effects or risks related to the taking or use of a drug, biological, product, or device.

Under current law, "eligible patient" means an individual who (1) has a terminal illness; (2) has considered all other FDA-approved treatment options; (3) has received a recommendation by the treating physician for the use of an investigational drug, biological product, or device; (4) has given informed consent; (5) is ineligible for or is unable to participate in a clinical trial; and (6) has documentation from the individual's treating physician that the individual meets other eligibility requirements.

The bill revises this definition to mean an individual who (1) has *a life-threatening* or *severely debilitating* illness; (2) has considered all other FDA-approved treatment options; (3) has received a recommendation from the individual's physician for an individualized investigational treatment based on an analysis of the individual's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products, or metabolites; (4) has given informed consent; and (5) has documentation from the individual's physician that the individual meets the other eligibility requirements. Ineligibility for or inability to participate in a clinical trial is removed from the definition, as is the requirement that a patient have a terminal illness.

Under current law, "informed consent" means a written document prepared using the informed consent form developed by the Office of the Attorney General that (1) is signed by the patient or a parent or legal guardian of the patient; (2) is attested to by the patient's treating physician and a witness; and (3) satisfies, at a minimum, specified criteria and procedures.

The bill expands this definition by requiring that the informed consent form must (1) explain the currently approved products and treatments for the *life-threatening or severely debilitating illness* from which the patient suffers, including alternative procedures or courses of treatment, if known to the treating physician, that might be advantageous to the patient; (2) inform the provider and eligible patient of any known, anticipated, or *reasonably foreseeable* side effects, risks, or reported patient discomfort that is likely related to the treatment; and (3) include a statement describing the extent to which confidentiality of records that identify the patient will be maintained.

Under the bill, "eligible facility" means an institution operating under a federalwide assurance for the protection of human subjects in accordance with specified federal law. "Life-threatening" means (1) diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and (2) diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. "Severely debilitating" means diseases or conditions that cause major irreversible morbidity.

Additional Comments: The bill alters the Maryland Right to Try Act to authorize access to individualized investigational treatments instead of investigational drugs, biological products, and devices that are in the pipeline for FDA approval but have only received Phase 1 approval. Access to these investigational drugs, biological products, and devices is now available under federal law.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: None.

Information Source(s): Office of the Attorney General; Judiciary (Administrative Office of the Courts); Department of Budget and Management; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

Fiscal Note History: First Reader - February 29, 2024
km/jc Third Reader - March 19, 2024
Revised - Amendment(s) - March 19, 2024

Analysis by: Ralph W. Kettell

Direct Inquiries to:
(410) 946-5510
(301) 970-5510