Department of Legislative Services

Maryland General Assembly
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FISCAL AND POLICY NOTE
First Reader

Senate Bill 63 (Senator Simonaire)
Finance

Investigational Drugs, Biological Products, and Devices - Right to Try Act

This bill permits a manufacturer of an "investigational drug, biological product, or device" to provide the investigational drug, biological product, or device to an "eligible patient." The manufacturer may provide the drug, biological product, or device without compensation, or charge the patient for the cost of, or associated with, the manufacture of the drug, biological product, or device.

Fiscal Summary

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

Local Effect: The bill is not anticipated to materially affect local government operations or finances.

Small Business Effect: Potential meaningful impact on producers of investigational drugs, biological products, or devices as discussed below.

Analysis

Bill Summary: An "investigational drug, biological product, or device" has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the U.S. Food and Drug Administration (FDA) and remains under investigation in an FDA-approved clinical trial. An "eligible patient" means an individual who has (1) a terminal illness; (2) considered all other treatment options currently approved by FDA; (3) received a recommendation by the treating physician for the use of an investigational drug, biological product, or device; (4) given informed consent or, if the individual is a minor or lacks the mental capacity to provide informed consent, the parent or legal guardian

has given informed consent; and (5) documentation from the individual's treating physician that the individual meets the other eligibility requirements. "Terminal illness" means a disease or condition that will result in death or a state of permanent unconsciousness from which recovery is unlikely within 12 months without life-sustaining procedures. "Informed consent" means a written document that must be signed by the patient or a parent or legal guardian of the patient, as well as the treating physician and a witness. The document must meet specified criteria, including:

- making clear that the patient's health insurance carrier and health care provider are not obligated to pay for any care or treatments that may be necessary as a result of the use of the investigational drug, biological product, or device unless specifically required to do so by law or contract;

- making clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device, and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements; and

- stating that the patient understands that he or she is liable for all expenses relating to the use of the investigational drug, biological product, or device, and that this liability extends to the patient's estate unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

Liability for Cost of Treatment: If the patient dies while undergoing treatment, the patient's *heirs* are not liable for any outstanding debt related to the treatment with an investigational drug, biological product, or device.

Prohibition on Sanctions: A health occupations board is prohibited from revoking, failing to renew, suspending, or taking any action against a health care provider's license based solely on the provider's recommendation to an eligible patient regarding an investigational drug, biological product, or device, as long as the recommendation was consistent with medical standards of care. Similarly, the Department of Health and Mental Hygiene may not take action against a health care provider's Medicare certification based solely on the provider's recommendation that an eligible patient have access to an investigational drug, biological product, or device.

Prohibition on Blocking Access: An official, employee, or agent of the State is prohibited from blocking or attempting to block an eligible patient's access to an investigational drug, biological product, or device. This does not prohibit a health care provider from providing counsel, advice, or a recommendation that is consistent with medical standards of care.

Manufacturer Immunity: The bill does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person involved in the care of the eligible patient, for any harm resulting from the investigational drug, biological product, or device if the manufacturer or other person is complying in good faith with the provisions of the bill and has exercised reasonable care.

Impact on Insurers and Insurance Policies: The bill does not affect the coverage requirements outlined in Title 15, Subtitle 8 of the Insurance Article.

Current Law/Background: Section 505 of the federal Food Drug and Cosmetic Act (FDCA) prohibits the sale or distribution of a drug into interstate commerce until the drug is proven safe and effective. Under FDA's Expanded Access Program, also referred to as "compassionate use," an investigational medical product (one that has not received FDA approval) may be used outside of a clinical trial. While the use of an investigational medical product as part of a clinical trial is preferable because clinical trials can generate data that may lead to the approval of products and, consequently, to wider availability, when enrolling a patient in a clinical trial is not possible (*i.e.*, a patient is not eligible or there are no clinical trials), patients may be able to receive the product, when appropriate, through expanded access. Since federal fiscal 2009, FDA's Expanded Access Program has received about 1,000 to 1,900 applications annually and nearly all were approved.

Under FDCA, a patient may seek individual access to investigational products for the diagnosis, monitoring, or treatment of a serious disease or condition if:

- the person's physician determines that there is no comparable or satisfactory alternative therapy available;

- the person's physician determines that the probable risk to the person from the investigational product is not greater than the probable risk from the disease or condition;

- FDA determines that there is sufficient evidence of the safety and effectiveness of the investigational product to support its use in the particular circumstance;

- FDA determines that providing the investigational product will not interfere with the initiation, conduct, or completion of clinical investigations; and

- the producer of the product or the clinical investigator submits a clinical protocol that is consistent with FDA's statute and applicable regulations for investigational new drugs or devices exemption applications, describing the use of the investigational product.

Additionally, a producer, clinical investigator, or physician may submit a protocol intended to provide widespread access to an investigational product under specified circumstances.

In February 2015, FDA released a draft guidance document explaining that FDA is moving to a new, "streamlined alternative" for submitting individual patient Expanded Access Program applications. The new form will be significantly simplified and ask for the patient's initials, clinical information about the patient, treatment information about the investigational drug and its planned use, and a letter of authorization from the drug company allowing the physician to use its product on the patient. The form will also ask for information about the physician as well as a certification by the physician that treatment will not begin for 30 days (the time it takes FDA to review submissions) unless emergency use procedures are followed. A physician may continue to request expanded access for patients in an emergency situation over the phone or by other rapid means of communication.

In 2013, the Goldwater Institute designed a model bill to create a state law path for terminally ill patients and their physicians to bypass FDCA and the FDA approval process and allow receipt of an investigational drug, biological product, or device before approval. Laws based on the model legislation are referred to as "Right to Try" (RTT) laws. RTT laws are currently in place in 24 states: Alabama, Arizona, Arkansas, Colorado, Florida, Illinois, Indiana, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, North Carolina, North Dakota, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Utah, Virginia, and Wyoming. In October 2015, California's RTT legislation was vetoed, citing the recent changes to the FDA Expanded Access Program. As of January 2016, 13 additional states, including Maryland, are considering RTT legislation. To date, there is no evidence that an individual has received an otherwise unapproved product under a state RTT law.

Small Business Effect: Maryland is home to a significant number of small pharmaceutical, biological product, and medical device producers, many located within the State's science and technology business parks or incubator programs, who may be impacted by the bill. While the bill does not require producers of investigational drugs, biological products, or devices to provide their products to eligible patients, producers may face public pressure to do so. Companies rarely produce more product than is necessary to complete a single phase of testing on the path toward FDA approval. As a result, a company pressured into providing its product to an individual outside of a clinical trial may face delays in completing its testing. Companies may also face financial consequences as a result of providing the investigational drug, biological product, or device or public backlash following a refusal to provide a product.

Additional Information

Prior Introductions: None.

Cross File: HB 56 (Delegate K. Young) - Health and Government Operations.

Information Source(s): U.S. Food and Drug Administration; Regulatory Affairs Professional Society; Health Policy Briefs: Right-to-Try Laws, *Health Affairs*, April 9, 2015; Judiciary (Administrative Office of the Courts); Department of Health and Mental Hygiene; Maryland Insurance Administration; Maryland Technology Development Corporation; Department of Legislative Services

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