Department of Legislative Services

Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
Enrolled - Revised

House Bill 584 (Delegate K. Young, *et al.*)
Health and Government Operations 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 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 provided to the patient.

Fiscal Summary

State Effect: The Office of the Attorney General (OAG) can handle the bill's requirements with existing budgeted resources. Revenues are not affected.

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; (5) been found ineligible for or unable to participate in a clinical trial; and (6) 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 prepared using the informed consent form developed by OAG in accordance with the bill 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:

- informing the provider and eligible patient of any known or anticipated side effects, risks, or reported patient discomfort that is likely related to the treatment;

- making clear that the patient's carrier and health care provider are not obligated to pay for any care or treatments that are necessary as a result of the use of the investigational drug, biological product, or device except as required by federal or State 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 may be 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, but not the heirs or legatees of the patient.

Informed Consent Form: OAG must develop an informed consent form that (1) complies with the bill's informed consent requirements; (2) includes instructions for the physician or patient on how to complete the form; and (3) provides spaces for a physician to include the information relating to a particular patient and the physician's recommendation for the patient. The development of an informed consent form may not be construed to prohibit a treating physician or a manufacturer of an investigational drug, biological product, or device from including additional information or advisements with the informed consent form.

Limits on Payment for Treatment: Any payment required by a manufacturer may not exceed the cost of manufacturing the specific investigational drug or biological product

dosages or devices provided. A manufacturer may not profit from providing an investigational drug, biological product, or device to an eligible patient.

Required Disclosure of Side Effects or Risks: After the date that an eligible patient begins taking or using the investigational drug, biological product, or device, and during the time of use, the manufacturer must notify the eligible patient and the eligible patient's health care provider of any side effects or risks associated with the investigational drug, biological product, or device that are required to be disclosed to FDA during the drug approval process.

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. 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 or the health care provider's treatment of an eligible patient with 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, which addresses required health insurance benefits.

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), a patient may be able to receive the product, when appropriate, through expanded access. Between federal fiscal 2009 and federal fiscal 2015, FDA's Expanded Access Program received between 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 June 2016, FDA released a revised form for individual patient Expanded Access Program applications. The new form is significantly simplified, includes step-by-step advice on its completion, and according to FDA takes approximately 45 minutes to complete. FDA advises that it authorizes over 99% of expanded access requests it receives, and that treatment may begin 30 days after FDA receives an application, or earlier if FDA notifies the treating physician that the expanded access use may begin.

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 33 states: Alabama, Arizona, Arkansas, California, Colorado,

Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Louisiana, Maine, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming. As of February 2017, 15 additional states, including Maryland, were considering RTT legislation.

Proposed Federal Legislation

Proposed federal RTT legislation, the Trickett Wendler Right to Try Act of 2017, would (1) prohibit the federal government from interfering with a state RTT law; (2) exempt a physician or drug company from liability for prescribing or providing an experimental drug, biological product, or device; and (3) prohibit 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 RTT act, to adversely impact the review or approval of the experimental drug, biological product, or device.

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, companies pressured into providing their product to individuals outside of a clinical trial may face delays in completing their 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: Similar legislation, SB 63 and HB 56 of 2016, was heard in the Senate Finance and House Health and Government Operations committees, respectively, and subsequently was withdrawn.

Cross File: SB 572 (Senator Simonaire, *et al.*) - Finance.

Information Source(s): U.S. Food and Drug Administration; Regulatory Affairs Professional Society; Department of Health and Mental Hygiene; Maryland Insurance Administration; Office of the Attorney General; righttotry.org; Department of Legislative Services

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