FINAL BILL REPORT
SSB 5035

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Synopsis as Enacted

Brief Description: Concerning patients' access to investigational medical products.

Sponsors: Senate Committee on Health Care (originally sponsored by Senators Pedersen, Rivers, Cleveland, Becker, Keiser, Walsh, Conway, Bailey, O'Ban, Mullet, Kuderer, Darneille and Wellman).

Senate Committee on Health Care
House Committee on Health Care & Wellness
House Committee on Appropriations

Background: The United States Food and Drug Administration (FDA) enforces the federal regulatory pathway for approval of medical therapies, including drugs. Until the FDA approves the drug for medical use, the drug may not be sold or distributed. Drugs typically undergo multiple phases of clinical trials to establish the drug's safety and efficacy. In Phase I, researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. Phase I clinical trials may last several months to a year. Phases II and III involve larger groups of people to further evaluate its safety, confirm its effectiveness, and collect new information to allow the drug to be used safely. Phases II and III may each take two or more years to complete.

If individuals do not qualify for a clinical trial but may benefit from treatment with an investigational drug, the FDA has an expanded access pathway that permits access to these drugs if: the individual has a serious or immediately life-threatening condition and there is no satisfactory alternative therapy, the potential benefit outweighs the treatment risks, and providing the investigational drug will not interfere with the clinical trial's process or compromise the product's development.

Right to try laws enable terminally ill patients to access experimental drugs, biologics, and devices that are still in a research phase and have not yet been approved for use by the FDA. In general, right to try laws permit patient access to an investigational drug if: the patient is terminally ill, a physician recommends use of the treatment, the patient provides informed consent, and the treatment has completed a Phase 1 clinical safety/dose limitation trial. They do not require that the patient be in a clinical trial or be otherwise approved by the FDA to use the drug.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Summary: Patients who are suffering from a serious or immediately life-threatening disease or condition may request a pharmaceutical manufacturer to make an investigational product available to the patient. In order to qualify for an investigational product, the patient must be at least 18 years old and be a Washington resident. The patient's treating physician must recommend treatment with the investigational product after informing the patient of FDA-approved treatment options. Finally, the patient must provide written, informed consent for the use of the investigational product.

Written, informed consent must include the following:

- an assertion that the patient has a serious or immediately life-threatening disease and currently approved treatments are unlikely to prolong the patient's life;
- potentially best and worst outcomes of the investigational product;
- a statement that the patient's health benefit plan is not obligated to pay for the investigational product or harm caused to the patient by the product; and
- that the patient is liable for all expenses consequent to the use of the investigational product.

The eligible patient and their treating physician may request that a drug manufacturer make an investigational product available for treatment of the patient. The manufacturer may, but is not required to, make the product available to the patient.

Health carriers may, but are not required to, provide coverage for the cost or the administration of an investigational product. The health carrier may deny coverage to an eligible patient who is treated with an investigational product from harm caused by the treatment. The health carrier is not required to cover costs associated with receiving the investigational product or costs associated with an adverse effect resulting from the product. The health carrier may not deny coverage for: the eligible patient's serious or immediately life-threatening disease or condition, benefits that accrued before the day on which the patient was treated with the investigational product, or palliative care for a patient who ceases treatment of the investigational product.

It is not an act of professional misconduct for a health care practitioner to recommend or administer an investigational product to an eligible patient.

Unless gross negligence or willful or wanton misconduct occurs, immunity from civil or criminal liability and administrative actions are provided to:

- health care practitioners who treat a patient with an investigational product;
- health care practitioners who recommend or request an investigational product or refuse to recommend or request an investigational product;
- manufacturers that provide investigational products to a health care practitioner;
- health care facilities where an investigational product is administered or provided to a patient; and
- health care facilities that do not allow health care providers to provide treatment with an investigational product or enforces a policy it has adopted regarding treatment with investigational products.

Votes on Final Passage:

Senate	49	0	
House	97	0	(House amended)
Senate	48	0	(Senate concurred)

Effective: July 23, 2017