S-4168.1

SENATE BILL 6550

State of Washington 64th Legislature 2016 Regular Session

By Senators Pedersen, Becker, Cleveland, Keiser, Frockt, Conway, Chase, Carlyle, and Roach

Read first time 01/26/16. Referred to Committee on Health Care.

AN ACT Relating to allowing access to investigational products by terminally ill patients participating in clinical trials; adding a new chapter to Title 69 RCW; and prescribing penalties.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** The legislature finds that the process for approval of investigational drugs, biological products, and devices in the United States protects future patients from premature, ineffective, and unsafe medications and treatments over time, but the process often takes many years. Patients who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States food and drug administration. The legislature further finds that patients who have a terminal illness should be permitted to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices. The use of available investigational drugs, biological products, and devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's health care provider so that the decision to use an investigational drug, biological product, or device is made with full awareness of the potential risks, benefits, and consequences to the patient and the patient's family.

The legislature, therefore, intends to allow terminally ill patients to use potentially lifesaving investigational drugs, biological products, and devices.

NEW SECTION. **Sec. 2.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1)(a) "Eligible patient" means a person has:

(i) A terminal illness, attested to by the patient's treating physician;

(ii) Considered all other treatment options currently approved by the United States food and drug administration;

(iii) Been unable to participate in a clinical trial that is located within one hundred miles of the patient's home address for the terminal illness, or not been accepted to the clinical trial within one week of completion of the clinical trial application process;

(iv) Received a recommendation from his or her physician for an investigational drug, biological product, or device;

(v) Given written, informed consent for the use of the investigational drug, biological product, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written, informed consent on the patient's behalf; and

(vi) Documentation from his or her physician that he or she meets the requirements of this subsection.

(b) "Eligible patient" does not include a person being treated as an inpatient in a hospital licensed under chapter 70.41 RCW.

(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States food and drug administration and remains under investigation in a United States food and drug administration-approved clinical trial.

(3) "Terminal illness" means a disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

(4) "Written, informed consent" means a written document signed by the patient and attested to by the patient's physician and a witness that, at a minimum:

(a) Explains the currently approved products and treatments for the disease or condition from which the patient suffers;

(b) Attests to the fact that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(c) Clearly identifies the specific proposed investigational drug, biological product, or device that the patient is seeking to use;

(d) Describes the potentially best and worst outcomes of using the investigational drug, biological product, or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result, and that death could be hastened by the proposed treatment, based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(e) Makes clear that the patient's health insurer and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device;

(f) Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements;

(g) Makes clear that in-home health care may be denied if treatment begins; and

(h) States that the patient understands that he or she is liable for all expenses consequent 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.

NEW SECTION. **Sec. 3.** (1) A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients under this chapter. This chapter does not require a manufacturer to make available an investigational drug, biological product, or device to an eligible patient.

(2) A manufacturer may:

(a) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(b) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

(3) A health insurance carrier may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device.

NEW SECTION. **Sec. 4.** It is not a violation of the uniform disciplinary act, chapter 18.130 RCW, if a physician recommends an eligible patient to seek access or treatment with an investigational drug, biological product, or device, as long as the recommendations are consistent with medical standards of care. No adverse action by the medical quality assurance commission or the board of osteopathic medicine and surgery may be taken against the license of a physician based solely on the physician's recommendation that a patient have access to an investigational drug, biological product, or device.

NEW SECTION. **Sec. 5.** (1) An official, employee, or agent of the state who blocks or attempts to block an eligible patient's access to an investigational drug, biological product, or device is guilty of a misdemeanor.

(2) Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

NEW SECTION. **Sec. 6.** This chapter does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, so long as the manufacturer or other person or entity exercises reasonable care and complies in good faith with this chapter.

NEW SECTION. **Sec. 7.** Sections 1 through 6 of this act constitute a new chapter in Title 69 RCW.

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