SUBSTITUTE SENATE BILL 5035

AS AMENDED BY THE HOUSE

Passed Legislature - 2017 Regular Session

State of Washington 65th Legislature 2017 Regular Session

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

READ FIRST TIME 02/03/17.

AN ACT Relating to patients' access to investigational medical products; amending RCW 69.04.570; reenacting and amending RCW 69.50.101; and adding a new chapter to Title 69 RCW.

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) "Eligible patient" means an individual who meets the requirements of section 4 of this act.

(2) "Health care facility" means a clinic, nursing home, laboratory, office, or similar place where a health care provider provides health care to patients.

(3) "Hospital" means a health care institution licensed under chapter 70.41, 71.12, or 72.23 RCW.

(4) "Investigational product" means a drug, biological product, or device that has successfully completed phase one and is currently in a subsequent phase of a clinical trial approved by the United States food and drug administration assessing the safety of the drug, biological product, or device under section 505 of the federal food, drug, and cosmetic act, 21 U.S.C. Sec. 355.

(5) "Issuer" means any state purchased health care programs under chapter 41.05 or 74.09 RCW, a disability insurer regulated under chapter 48.20 or 48.21 RCW, a health care service contractor as defined in RCW 48.44.010, or a health maintenance organization as defined in RCW 48.46.020.

(6) "Manufacturer" means a person or other entity engaged in the manufacture or distribution of drugs, biological products, or devices.

(7) "Physician" means a physician licensed under chapter 18.71 RCW or an osteopathic physician and surgeon licensed under chapter 18.57 RCW.

(8) "Serious or immediately life-threatening disease or condition" means a stage of disease in which there is reasonable likelihood that death will occur within six months or in which premature death is likely without early treatment.

NEW SECTION. **Sec. 3.** (1) An eligible patient and his or her treating physician may request that a manufacturer make an investigational product available for treatment of the patient. The request must include a copy of the written informed consent form

described in section 5 of this act and an explanation of why the treating physician believes the investigational product may help the patient.

(2) Upon receipt of the request and the written informed consent form, the manufacturer may, but is not required to, make the investigational product available for treatment of the eligible patient. Prior to making the investigational product available, the manufacturer shall enter into an agreement with the treating physician and the eligible patient providing that the manufacturer will transfer the investigational product to the physician and the physician will use the investigational product to treat the eligible patient.

NEW SECTION. **Sec. 4.** A patient is eligible to request access to and be treated with an investigational product if:

(1) The patient is eighteen years of age or older;

(2) The patient is a resident of this state;

(3) The patient's treating physician attests to the fact that the patient has a serious or immediately life-threatening disease or condition;

(4) The patient acknowledges having been informed by the treating physician of all other treatment options currently approved by the United States food and drug administration;

(5) The patient's treating physician recommends that the patient be treated with an investigational product;

(6) The patient is unable to participate in a clinical trial for the investigational product because the patient's physician has contacted one or more clinical trials or researchers in the physician's practice area and has determined, using the physician's professional judgment, that there are no clinical trials reasonably available for the patient to participate in, that the patient would not qualify for a clinical trial, or that delay in waiting to join a clinical trial would risk further harm to the patient; and

(7) In accordance with section 5 of this act, the patient has provided written informed consent for the use of the investigational product, or, if the patient lacks the capacity to consent, the patient's legally authorized representative has provided written informed consent on behalf of the patient.

NEW SECTION. **Sec. 5.** (1) Prior to treatment of the eligible patient with an investigational product, the treating physician shall obtain written informed consent, consistent with the requirements of RCW 7.70.060(1), and signed by the eligible patient or, if the patient lacks the capacity to consent, his or her legally authorized representative.

(2) Information provided in order to obtain the informed consent must, to the extent possible, include the following:

(a) That the patient has been diagnosed with a serious or immediately life-threatening disease or condition and explains the currently approved products and treatments for the disease or condition from which the eligible patient suffers;

(b) That all currently approved and conventionally recognized treatments are unlikely to prolong the eligible patient's life;

(c) Clear identification of the investigational product that the eligible patient seeks to use;

(d) The potentially best and worst outcomes of using the investigational product and a realistic description of the most likely outcome. This description must include the possibility that new, unanticipated, different, or worse symptoms may result and that death could be hastened by the proposed treatment. The description must be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the eligible patient's condition;

(e) That the eligible patient's health benefit plan is not obligated to pay for the investigational product or any harm caused to the eligible patient by the investigational product, unless otherwise specifically required to do so by law or contract, and that in order to receive the investigational product the patient may be required to pay the costs of administering the investigational product; and

(f) That the eligible patient is liable for all expenses consequent to the use of the investigational product, except as otherwise provided in the eligible patient's health benefit plan or a contract between the eligible patient and the manufacturer of the investigational product.

(3) The document must be signed and dated by the eligible patient's treating physician and witnessed in writing by at least one adult.

NEW SECTION. **Sec. 6.** (1) An issuer may, but is not required to, provide coverage for the cost or the administration of an investigational product provided to an eligible patient pursuant to this chapter.

(2)(a) An issuer may deny coverage to an eligible patient who is treated with an investigational product for harm to the eligible patient caused by the investigational product and is not required to cover the costs associated with receiving the investigational product or the costs demonstrated to be associated with an adverse effect that is a result of receiving the investigational product.

(b) Except as stated in (a) of this subsection, an issuer may not deny coverage to an eligible patient for: (i) The eligible patient's serious or immediately life-threatening disease or condition; (ii) benefits that accrued before the day on which the eligible patient was treated with an investigational product; or (iii) palliative or hospice care for an eligible patient who was previously treated with an investigational product but who is no longer being treated with an investigational product.

NEW SECTION. **Sec. 7.** A hospital or health care facility:

(1) May, but is not required to, allow a health care practitioner who is privileged to practice or who is employed at the hospital or health care facility to treat, administer, or provide an investigational product to an eligible patient under this chapter;

(2) May establish a policy regarding treating, administering, or providing investigational products under this chapter; and

(3) Is not obligated to pay for the investigational product or any harm caused to the eligible patient by the product, or any care that is necessary as a result of the use of the investigational product, including under chapter 70.170 RCW.

NEW SECTION. **Sec. 8.** (1) This act does not create a private right of action.

(2) A health care practitioner does not commit unprofessional conduct under RCW 18.130.180 and does not violate the applicable standard of care by:

(a) Obtaining an investigational product pursuant to this chapter;

(b) Refusing to recommend, request, prescribe, or otherwise provide an investigational product pursuant to this chapter;

(c) Administering an investigational product to an eligible patient pursuant to this chapter; or

(d) Treating an eligible patient with an investigational product pursuant to this chapter.

(3) The following persons and entities are immune from civil or criminal liability and administrative actions arising out of treatment of an eligible patient with an investigational product, other than acts or omissions constituting gross negligence or willful or wanton misconduct:

(a) A health care practitioner who recommends or requests an investigational product for an eligible patient in compliance with this chapter;

(b) A health care practitioner who refuses to recommend or request an investigational product for a patient seeking access to an investigational product;

(c) A manufacturer that provides an investigational product to a health care practitioner in compliance with this chapter;

(d) A hospital or health care facility where an investigational product is either administered or provided to an eligible patient in compliance with this chapter; and

(e) A hospital or health care facility that does not allow a health care practitioner to provide treatment with an investigational product or enforces a policy it has adopted regarding treating, administering, or providing care with an investigational product.

NEW SECTION. **Sec. 9.** The pharmacy quality assurance commission may adopt rules necessary to implement this chapter.

Sec. 10. RCW 69.04.570 and 2012 c 117 s 338 are each amended to read as follows:

Except as permitted by chapter 69.--- RCW (the new chapter created in section 12 of this act), no person shall introduce or deliver for introduction into intrastate commerce any new drug which is subject to section 505 of the federal act unless an application with respect to such drug has become effective thereunder. No person shall introduce or deliver for introduction into intrastate commerce any new drug which is not subject to section 505 of the federal act, unless (1) it has been found, by appropriate tests, that such drug is not unsafe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; and (2) an application has been

filed under this section of this chapter with respect to such drug: PROVIDED, That the requirement of subsection (2) of this section shall not apply to any drug introduced into intrastate commerce at any time prior to the enactment of this chapter or introduced into interstate commerce at any time prior to the enactment of the federal act: PROVIDED FURTHER, That if the director finds that the requirement of subsection (2) of this section as applied to any drug or class of drugs, is not necessary for the protection of the public health, he or she shall promulgate regulations of exemption accordingly.

Sec. 11. RCW 69.50.101 and 2015 2nd sp.s. c 4 s 901 are each reenacted and amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(a) "Administer" means to apply a controlled substance, whether by injection, inhalation, ingestion, or any other means, directly to the body of a patient or research subject by:

(1) a practitioner authorized to prescribe (or, by the practitioner's authorized agent); or

(2) the patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseperson, or employee of the carrier or warehouseperson.

(c) "CBD concentration" has the meaning provided in RCW 69.51A.010.

(d) "Commission" means the pharmacy quality assurance commission.

(e) "Controlled substance" means a drug, substance, or immediate precursor included in Schedules I through V as set forth in federal or state laws, or federal or commission rules.

(f)(1) "Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and:

(i) that has a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II; or

(ii) with respect to a particular individual, that the individual represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II.

(2) The term does not include:

(i) a controlled substance;

(ii) a substance for which there is an approved new drug application;

(iii) a substance with respect to which an exemption is in effect for investigational use by a particular person under section 505 of the federal food, drug, and cosmetic act, 21 U.S.C. Sec. 355, or chapter 69.--- RCW (the new chapter created in section 12 of this act) to the extent conduct with respect to the substance is pursuant to the exemption; or

(iv) any substance to the extent not intended for human consumption before an exemption takes effect with respect to the substance.

(g) "Deliver" or "delivery((~~r~~))" means the actual or constructive transfer from one person to another of a substance, whether or not there is an agency relationship.

(h) "Department" means the department of health.

(i) "Designated provider" has the meaning provided in RCW 69.51A.010.

(j) "Dispense" means the interpretation of a prescription or order for a controlled substance and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(k) "Dispenser" means a practitioner who dispenses.

(l) "Distribute" means to deliver other than by administering or dispensing a controlled substance.

(m) "Distributor" means a person who distributes.

(n) "Drug" means (1) a controlled substance recognized as a drug in the official United States pharmacopoeia/national formulary or the official homeopathic pharmacopoeia of the United States, or any supplement to them; (2) controlled substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; (3) controlled substances (other than food)

intended to affect the structure or any function of the body of individuals or animals; and (4) controlled substances intended for use as a component of any article specified in (1), (2), or (3) of this subsection. The term does not include devices or their components, parts, or accessories.

(o) "Drug enforcement administration" means the drug enforcement administration in the United States Department of Justice, or its successor agency.

(p) "Electronic communication of prescription information" means the transmission of a prescription or refill authorization for a drug of a practitioner using computer systems. The term does not include a prescription or refill authorization verbally transmitted by telephone nor a facsimile manually signed by the practitioner.

(q) "Immediate precursor" means a substance:

(1) that the commission has found to be and by rule designates as being the principal compound commonly used, or produced primarily for use, in the manufacture of a controlled substance;

(2) that is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance; and

(3) the control of which is necessary to prevent, curtail, or limit the manufacture of the controlled substance.

(r) "Isomer" means an optical isomer, but in subsection (dd)(5) of this section, RCW 69.50.204(a) (12) and (34), and 69.50.206(b)(4), the term includes any geometrical isomer; in RCW 69.50.204(a) (8) and (42), and 69.50.210(c) the term includes any positional isomer; and in RCW 69.50.204(a)(35), 69.50.204(c), and 69.50.208(a) the term includes any positional or geometric isomer.

(s) "Lot" means a definite quantity of marijuana, marijuana concentrates, useable marijuana, or marijuana-infused product identified by a lot number, every portion or package of which is uniform within recognized tolerances for the factors that appear in the labeling.

(t) "Lot number" must identify the licensee by business or trade name and Washington state unified business identifier number, and the date of harvest or processing for each lot of marijuana, marijuana concentrates, useable marijuana, or marijuana-infused product.

(u) "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or

by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. The term does not include the preparation, compounding, packaging, repackaging, labeling, or relabeling of a controlled substance:

(1) by a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or

(2) by a practitioner, or by the practitioner's authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

(v) "Marijuana" or "marihuana" means all parts of the plant *Cannabis*, whether growing or not, with a THC concentration greater than 0.3 percent on a dry weight basis; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

(w) "Marijuana concentrates" means products consisting wholly or in part of the resin extracted from any part of the plant *Cannabis* and having a THC concentration greater than ten percent.

(x) "Marijuana processor" means a person licensed by the state liquor and cannabis board to process marijuana into marijuana concentrates, useable marijuana, and marijuana-infused products, package and label marijuana concentrates, useable marijuana, and marijuana-infused products for sale in retail outlets, and sell marijuana concentrates, useable marijuana, and marijuana-infused products at wholesale to marijuana retailers.

(y) "Marijuana producer" means a person licensed by the state liquor and cannabis board to produce and sell marijuana at wholesale to marijuana processors and other marijuana producers.

(z) "Marijuana products" means useable marijuana, marijuana concentrates, and marijuana-infused products as defined in this section.

(aa) "Marijuana researcher" means a person licensed by the state liquor and cannabis board to produce, process, and possess marijuana for the purposes of conducting research on marijuana and marijuana-derived drug products.

(bb) "Marijuana retailer" means a person licensed by the state liquor and cannabis board to sell marijuana concentrates, useable marijuana, and marijuana-infused products in a retail outlet.

(cc) "Marijuana-infused products" means products that contain marijuana or marijuana extracts, are intended for human use, are derived from marijuana as defined in subsection (v) of this section, and have a THC concentration no greater than ten percent. The term "marijuana-infused products" does not include either useable marijuana or marijuana concentrates.

(dd) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium, opium derivative, and any derivative of opium or opium derivative, including their salts, isomers, and salts of isomers, whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation. The term does not include the isoquinoline alkaloids of opium.

(2) Synthetic opiate and any derivative of synthetic opiate, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation.

(3) Poppy straw and concentrate of poppy straw.

(4) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives or ecgonine or their salts have been removed.

(5) Cocaine, or any salt, isomer, or salt of isomer thereof.

(6) Cocaine base.

(7) Ecgonine, or any derivative, salt, isomer, or salt of isomer thereof.

(8) Any compound, mixture, or preparation containing any quantity of any substance referred to in subparagraphs (1) through (7).

(ee) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-

sustaining liability. The term includes opium, substances derived from opium (opium derivatives), and synthetic opiates. The term does not include, unless specifically designated as controlled under RCW 69.50.201, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). The term includes the racemic and levorotatory forms of dextromethorphan.

(ff) "Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.

(gg) "Person" means individual, corporation, business trust, estate, trust, partnership, association, joint venture, government, governmental subdivision or agency, or any other legal or commercial entity.

(hh) "Plant" has the meaning provided in RCW 69.51A.010.

(ii) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(jj) "Practitioner" means:

(1) A physician under chapter 18.71 RCW; a physician assistant under chapter 18.71A RCW; an osteopathic physician and surgeon under chapter 18.57 RCW; an osteopathic physician assistant under chapter 18.57A RCW who is licensed under RCW 18.57A.020 subject to any limitations in RCW 18.57A.040; an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010 subject to any limitations in RCW 18.53.010; a dentist under chapter 18.32 RCW; a podiatric physician and surgeon under chapter 18.22 RCW; a veterinarian under chapter 18.92 RCW; a registered nurse, advanced registered nurse practitioner, or licensed practical nurse under chapter 18.79 RCW; a naturopathic physician under chapter 18.36A RCW who is licensed under RCW 18.36A.030 subject to any limitations in RCW 18.36A.040; a pharmacist under chapter 18.64 RCW or a scientific investigator under this chapter, licensed, registered or otherwise permitted insofar as is consistent with those licensing laws to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of their professional practice or research in this state.

(2) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

(3) A physician licensed to practice medicine and surgery, a physician licensed to practice osteopathic medicine and surgery, a

dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, a licensed physician assistant or a licensed osteopathic physician assistant specifically approved to prescribe controlled substances by his or her state's medical quality assurance commission or equivalent and his or her supervising physician, an advanced registered nurse practitioner licensed to prescribe controlled substances, or a veterinarian licensed to practice veterinary medicine in any state of the United States.

(kk) "Prescription" means an order for controlled substances issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe controlled substances within the scope of his or her professional practice for a legitimate medical purpose.

(ll) "Production" includes the manufacturing, planting, cultivating, growing, or harvesting of a controlled substance.

(mm) "Qualifying patient" has the meaning provided in RCW 69.51A.010.

(nn) "Recognition card" has the meaning provided in RCW 69.51A.010.

(oo) "Retail outlet" means a location licensed by the state liquor and cannabis board for the retail sale of marijuana concentrates, useable marijuana, and marijuana-infused products.

(pp) "Secretary" means the secretary of health or the secretary's designee.

(qq) "State," unless the context otherwise requires, means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(rr) "THC concentration" means percent of delta-9 tetrahydrocannabinol content per dry weight of any part of the plant *Cannabis*, or per volume or weight of marijuana product, or the combined percent of delta-9 tetrahydrocannabinol and tetrahydrocannabinolic acid in any part of the plant *Cannabis* regardless of moisture content.

(ss) "Ultimate user" means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household or for administering to an animal owned by the individual or by a member of the individual's household.

(tt) "Useable marijuana" means dried marijuana flowers. The term "useable marijuana" does not include either marijuana-infused products or marijuana concentrates.

NEW SECTION. **Sec. 12.** Sections 1 through 9 of this act constitute a new chapter in Title 69 RCW.

NEW SECTION. **Sec. 13.** If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

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