
SUBSTITUTE SENATE BILL 6550

State of Washington

64th Legislature

2016 Regular Session

By Senate Health Care (originally sponsored by Senators Pedersen, Becker, Cleveland, Keiser, Frockt, Conway, Chase, Carlyle, and Roach)

READ FIRST TIME 02/05/16.

1 AN ACT Relating to patients' access to investigational medical
2 products; amending RCW 69.04.570; reenacting and amending RCW
3 69.50.101; and adding a new chapter to Title 69 RCW.

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

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

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

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

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

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

15 (3) "Issuer" means a disability insurer regulated under chapter
16 48.20 or 48.21 RCW, a health care service contractor as defined in
17 RCW 48.44.010, or a health maintenance organization as defined in RCW
18 48.46.020.

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

22 (5) "Physician" means a physician licensed under chapter 18.71
23 RCW or an osteopathic physician and surgeon licensed under chapter
24 18.57 RCW.

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

29 NEW SECTION. **Sec. 3.** (1) An eligible patient and his or her
30 treating physician may request that a manufacturer make an
31 investigational product available for treatment of the patient. The
32 request must include a copy of the written informed consent form
33 described in section 5 of this act and an explanation of why the
34 treating physician believes the investigational product may help the
35 patient.

36 (2) Upon receipt of the request and the written informed consent
37 form, the manufacturer may, but is not required to, make the
38 investigational product available for treatment of the eligible

1 patient. Prior to making the investigational product available, the
2 manufacturer shall enter into an agreement with the treating
3 physician and the eligible patient providing that the manufacturer
4 will transfer the investigational product to the physician and the
5 physician will use the investigational product to treat the eligible
6 patient.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

35 (b) Except as stated in (a) of this subsection, an issuer may not
36 deny coverage to an eligible patient for: (i) The eligible patient's
37 serious or immediately life-threatening disease or condition; (ii)
38 benefits that accrued before the day on which the eligible patient
39 was treated with an investigational product; or (iii) palliative or

1 hospice care for an eligible patient who was previously treated with
2 an investigational product but who is no longer being treated with an
3 investigational product.

4 NEW SECTION. **Sec. 7.** (1) This act does not create a private
5 right of action.

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

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

11 (b) Administering an investigational product to an eligible
12 patient pursuant to this chapter; or

13 (c) Treating an eligible patient with an investigational product
14 pursuant to this chapter.

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

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

22 (b) A manufacturer that provides an investigational product to a
23 health care practitioner in compliance with this chapter.

24 (4) The protections and immunities set forth in this section also
25 apply in situations in which a health care practitioner denies a
26 patient's request for a treatment with an investigational product,
27 either because the health care practitioner believes there are more
28 effective treatments available or because the requested treatment is
29 not likely to be beneficial.

30 NEW SECTION. **Sec. 8.** The pharmacy quality assurance commission
31 may adopt rules necessary to implement this chapter.

32 **Sec. 9.** RCW 69.04.570 and 2012 c 117 s 338 are each amended to
33 read as follows:

34 Except as permitted by chapter 69.--- RCW (the new chapter
35 created in section 11 of this act), no person shall introduce or
36 deliver for introduction into intrastate commerce any new drug which
37 is subject to section 505 of the federal act unless an application

1 with respect to such drug has become effective thereunder. No person
2 shall introduce or deliver for introduction into intrastate commerce
3 any new drug which is not subject to section 505 of the federal act,
4 unless (1) it has been found, by appropriate tests, that such drug is
5 not unsafe for use under the conditions prescribed, recommended, or
6 suggested in the labeling thereof; and (2) an application has been
7 filed under this section of this chapter with respect to such drug:
8 PROVIDED, That the requirement of subsection (2) of this section
9 shall not apply to any drug introduced into intrastate commerce at
10 any time prior to the enactment of this chapter or introduced into
11 interstate commerce at any time prior to the enactment of the federal
12 act: PROVIDED FURTHER, That if the director finds that the
13 requirement of subsection (2) of this section as applied to any drug
14 or class of drugs, is not necessary for the protection of the public
15 health, he or she shall promulgate regulations of exemption
16 accordingly.

17 **Sec. 10.** RCW 69.50.101 and 2015 2nd sp.s. c 4 s 901 are each
18 reenacted and amended to read as follows:

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

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

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

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

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

32 (c) "CBD concentration" has the meaning provided in RCW
33 69.51A.010.

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

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

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

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

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

14 (2) The term does not include:

15 (i) a controlled substance;

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

18 (iii) a substance with respect to which an exemption is in effect
19 for investigational use by a particular person under section 505 of
20 the federal food, drug, and cosmetic act, 21 U.S.C. Sec. 355, or
21 chapter 69.--- RCW (the new chapter created in section 11 of this
22 act) to the extent conduct with respect to the substance is pursuant
23 to the exemption; or

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

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

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

31 (i) "Designated provider" has the meaning provided in RCW
32 69.51A.010.

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

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

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

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

2 (n) "Drug" means (1) a controlled substance recognized as a drug
3 in the official United States pharmacopoeia/national formulary or the
4 official homeopathic pharmacopoeia of the United States, or any
5 supplement to them; (2) controlled substances intended for use in the
6 diagnosis, cure, mitigation, treatment, or prevention of disease in
7 individuals or animals; (3) controlled substances (other than food)
8 intended to affect the structure or any function of the body of
9 individuals or animals; and (4) controlled substances intended for
10 use as a component of any article specified in (1), (2), or (3) of
11 this subsection. The term does not include devices or their
12 components, parts, or accessories.

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

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

21 (q) "Immediate precursor" means a substance:
22 (1) that the commission has found to be and by rule designates as
23 being the principal compound commonly used, or produced primarily for
24 use, in the manufacture of a controlled substance;
25 (2) that is an immediate chemical intermediary used or likely to
26 be used in the manufacture of a controlled substance; and
27 (3) the control of which is necessary to prevent, curtail, or
28 limit the manufacture of the controlled substance.

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

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

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

5 (u) "Manufacture" means the production, preparation, propagation,
6 compounding, conversion, or processing of a controlled substance,
7 either directly or indirectly or by extraction from substances of
8 natural origin, or independently by means of chemical synthesis, or
9 by a combination of extraction and chemical synthesis, and includes
10 any packaging or repackaging of the substance or labeling or
11 relabeling of its container. The term does not include the
12 preparation, compounding, packaging, repackaging, labeling, or
13 relabeling of a controlled substance:

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

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

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

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

35 (x) "Marijuana processor" means a person licensed by the state
36 liquor and cannabis board to process marijuana into marijuana
37 concentrates, useable marijuana, and marijuana-infused products,
38 package and label marijuana concentrates, useable marijuana, and
39 marijuana-infused products for sale in retail outlets, and sell

1 marijuana concentrates, useable marijuana, and marijuana-infused
2 products at wholesale to marijuana retailers.

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

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

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

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

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

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

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

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

36 (3) Poppy straw and concentrate of poppy straw.

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

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

1 (6) Cocaine base.

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

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

6 (ee) "Opiate" means any substance having an addiction-forming or
7 addiction-sustaining liability similar to morphine or being capable
8 of conversion into a drug having addiction-forming or addiction-
9 sustaining liability. The term includes opium, substances derived
10 from opium (opium derivatives), and synthetic opiates. The term does
11 not include, unless specifically designated as controlled under RCW
12 69.50.201, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan
13 and its salts (dextromethorphan). The term includes the racemic and
14 levorotatory forms of dextromethorphan.

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

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

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

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

24 (jj) "Practitioner" means:

25 (1) A physician under chapter 18.71 RCW; a physician assistant
26 under chapter 18.71A RCW; an osteopathic physician and surgeon under
27 chapter 18.57 RCW; an osteopathic physician assistant under chapter
28 18.57A RCW who is licensed under RCW 18.57A.020 subject to any
29 limitations in RCW 18.57A.040; an optometrist licensed under chapter
30 18.53 RCW who is certified by the optometry board under RCW 18.53.010
31 subject to any limitations in RCW 18.53.010; a dentist under chapter
32 18.32 RCW; a podiatric physician and surgeon under chapter 18.22 RCW;
33 a veterinarian under chapter 18.92 RCW; a registered nurse, advanced
34 registered nurse practitioner, or licensed practical nurse under
35 chapter 18.79 RCW; a naturopathic physician under chapter 18.36A RCW
36 who is licensed under RCW 18.36A.030 subject to any limitations in
37 RCW 18.36A.040; a pharmacist under chapter 18.64 RCW or a scientific
38 investigator under this chapter, licensed, registered or otherwise
39 permitted insofar as is consistent with those licensing laws to
40 distribute, dispense, conduct research with respect to or administer

1 a controlled substance in the course of their professional practice
2 or research in this state.

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

7 (3) A physician licensed to practice medicine and surgery, a
8 physician licensed to practice osteopathic medicine and surgery, a
9 dentist licensed to practice dentistry, a podiatric physician and
10 surgeon licensed to practice podiatric medicine and surgery, a
11 licensed physician assistant or a licensed osteopathic physician
12 assistant specifically approved to prescribe controlled substances by
13 his or her state's medical quality assurance commission or equivalent
14 and his or her supervising physician, an advanced registered nurse
15 practitioner licensed to prescribe controlled substances, or a
16 veterinarian licensed to practice veterinary medicine in any state of
17 the United States.

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

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

24 (mm) "Qualifying patient" has the meaning provided in RCW
25 69.51A.010.

26 (nn) "Recognition card" has the meaning provided in RCW
27 69.51A.010.

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

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

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

37 (rr) "THC concentration" means percent of delta-9
38 tetrahydrocannabinol content per dry weight of any part of the plant
39 *Cannabis*, or per volume or weight of marijuana product, or the
40 combined percent of delta-9 tetrahydrocannabinol and

1 tetrahydrocannabinolic acid in any part of the plant *Cannabis*
2 regardless of moisture content.

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

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

11 NEW SECTION. **Sec. 11.** Sections 1 through 8 of this act
12 constitute a new chapter in Title 69 RCW.

13 NEW SECTION. **Sec. 12.** If any provision of this act or its
14 application to any person or circumstance is held invalid, the
15 remainder of the act or the application of the provision to other
16 persons or circumstances is not affected.

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