
HOUSE BILL 2961

State of Washington

64th Legislature

2016 Regular Session

By Representatives Vick, Schmick, and Short

Read first time 02/01/16. Referred to Committee on Health Care & Wellness.

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

8 (1) "Eligible patient" means an individual who meets the
9 requirements of section 3 of this act.

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

16 (3) "Issuer" means a disability insurer regulated under chapter
17 48.20 or 48.21 RCW, a health care service contractor as defined in
18 RCW 48.44.010, or a health maintenance organization as defined in RCW
19 48.46.020.

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

4 (5) "Physician" means a physician licensed under chapter 18.71
5 RCW or an osteopathic physician and surgeon licensed under chapter
6 18.57 RCW.

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

11 NEW SECTION. **Sec. 2.** (1) An eligible patient and his or her
12 treating physician may request that a manufacturer make an
13 investigational product available for treatment of the patient. The
14 request must include a copy of the written informed consent form
15 described in section 4 of this act and an explanation of why the
16 treating physician believes the investigational product may help the
17 patient.

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

27 NEW SECTION. **Sec. 3.** A patient is eligible to request access to
28 and be treated with an investigational product if:

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

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

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

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

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

1 (6) In accordance with section 4 of this act, the patient has
2 provided written informed consent for the use of the investigational
3 product, or, if the patient lacks the capacity to consent, the
4 patient's legally authorized representative has provided written
5 informed consent on behalf of the patient.

6 NEW SECTION. **Sec. 4.** (1) Prior to treatment of the eligible
7 patient with an investigational product, the treating physician shall
8 obtain written informed consent, consistent with the requirements of
9 RCW 7.70.060(1), and signed by the eligible patient or, if the
10 patient lacks the capacity to consent, his or her legally authorized
11 representative.

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

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

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

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

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

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

36 (f) That the eligible patient is liable for all expenses
37 consequent to the use of the investigational product, except as
38 otherwise provided in the eligible patient's health benefit plan or a

1 contract between the eligible patient and the manufacturer of the
2 investigational product.

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

6 NEW SECTION. **Sec. 5.** (1) An issuer may, but is not required to,
7 provide coverage for the cost or the administration of an
8 investigational product provided to an eligible patient pursuant to
9 this chapter.

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

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

24 NEW SECTION. **Sec. 6.** (1) This act does not create a private
25 right of action.

26 (2) A physician does not commit unprofessional conduct under RCW
27 18.130.180 and does not violate the applicable standard of care by:

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

30 (b) Administering an investigational product to an eligible
31 patient pursuant to this chapter; or

32 (c) Treating an eligible patient with an investigational product
33 pursuant to this chapter.

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

1 (a) A physician who recommends or requests an investigational
2 product for an eligible patient in compliance with this chapter; and

3 (b) A manufacturer that provides an investigational product to a
4 physician in compliance with this chapter.

5 (4) The protections and immunities set forth in this section also
6 apply in situations in which a physician denies a patient's request
7 for a treatment with an investigational product, either because the
8 physician believes there are more effective treatments available or
9 because the requested treatment is not likely to be beneficial.

10 NEW SECTION. **Sec. 7.** The pharmacy quality assurance commission
11 may adopt rules necessary to implement this chapter.

12 **Sec. 8.** RCW 69.04.570 and 2012 c 117 s 338 are each amended to
13 read as follows:

14 Except as permitted by chapter 69.--- RCW (the new chapter
15 created in section 10 of this act), no person shall introduce or
16 deliver for introduction into intrastate commerce any new drug which
17 is subject to section 505 of the federal act unless an application
18 with respect to such drug has become effective thereunder. No person
19 shall introduce or deliver for introduction into intrastate commerce
20 any new drug which is not subject to section 505 of the federal act,
21 unless (1) it has been found, by appropriate tests, that such drug is
22 not unsafe for use under the conditions prescribed, recommended, or
23 suggested in the labeling thereof; and (2) an application has been
24 filed under this section of this chapter with respect to such drug:
25 PROVIDED, That the requirement of subsection (2) of this section
26 shall not apply to any drug introduced into intrastate commerce at
27 any time prior to the enactment of this chapter or introduced into
28 interstate commerce at any time prior to the enactment of the federal
29 act: PROVIDED FURTHER, That if the director finds that the
30 requirement of subsection (2) of this section as applied to any drug
31 or class of drugs, is not necessary for the protection of the public
32 health, he or she shall promulgate regulations of exemption
33 accordingly.

34 **Sec. 9.** RCW 69.50.101 and 2015 2nd sp.s. c 4 s 901 are each
35 reenacted and amended to read as follows:

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

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

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

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

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

12 (c) "CBD concentration" has the meaning provided in RCW
13 69.51A.010.

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

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

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

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

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

31 (2) The term does not include:

32 (i) a controlled substance;

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

35 (iii) a substance with respect to which an exemption is in effect
36 for investigational use by a particular person under section 505 of
37 the federal food, drug, and cosmetic act, 21 U.S.C. Sec. 355, or
38 chapter 69.--- RCW (the new chapter created in section 10 of this
39 act) to the extent conduct with respect to the substance is pursuant
40 to the exemption; or

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

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

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

8 (i) "Designated provider" has the meaning provided in RCW
9 69.51A.010.

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

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

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

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

19 (n) "Drug" means (1) a controlled substance recognized as a drug
20 in the official United States pharmacopoeia/national formulary or the
21 official homeopathic pharmacopoeia of the United States, or any
22 supplement to them; (2) controlled substances intended for use in the
23 diagnosis, cure, mitigation, treatment, or prevention of disease in
24 individuals or animals; (3) controlled substances (other than food)
25 intended to affect the structure or any function of the body of
26 individuals or animals; and (4) controlled substances intended for
27 use as a component of any article specified in (1), (2), or (3) of
28 this subsection. The term does not include devices or their
29 components, parts, or accessories.

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

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

38 (q) "Immediate precursor" means a substance:

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

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

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

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

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

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

23 (u) "Manufacture" means the production, preparation, propagation,
24 compounding, conversion, or processing of a controlled substance,
25 either directly or indirectly or by extraction from substances of
26 natural origin, or independently by means of chemical synthesis, or
27 by a combination of extraction and chemical synthesis, and includes
28 any packaging or repackaging of the substance or labeling or
29 relabeling of its container. The term does not include the
30 preparation, compounding, packaging, repackaging, labeling, or
31 relabeling of a controlled substance:

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

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

39 (v) "Marijuana" or "marihuana" means all parts of the plant
40 *Cannabis*, whether growing or not, with a THC concentration greater

1 than 0.3 percent on a dry weight basis; the seeds thereof; the resin
2 extracted from any part of the plant; and every compound,
3 manufacture, salt, derivative, mixture, or preparation of the plant,
4 its seeds or resin. The term does not include the mature stalks of
5 the plant, fiber produced from the stalks, oil or cake made from the
6 seeds of the plant, any other compound, manufacture, salt,
7 derivative, mixture, or preparation of the mature stalks (except the
8 resin extracted therefrom), fiber, oil, or cake, or the sterilized
9 seed of the plant which is incapable of germination.

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

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

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

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

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

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

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

39 (dd) "Narcotic drug" means any of the following, whether produced
40 directly or indirectly by extraction from substances of vegetable

1 origin, or independently by means of chemical synthesis, or by a
2 combination of extraction and chemical synthesis:

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

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

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

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

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

18 (6) Cocaine base.

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

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

23 (ee) "Opiate" means any substance having an addiction-forming or
24 addiction-sustaining liability similar to morphine or being capable
25 of conversion into a drug having addiction-forming or addiction-
26 sustaining liability. The term includes opium, substances derived
27 from opium (opium derivatives), and synthetic opiates. The term does
28 not include, unless specifically designated as controlled under RCW
29 69.50.201, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan
30 and its salts (dextromethorphan). The term includes the racemic and
31 levorotatory forms of dextromethorphan.

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

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

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

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

1 (jj) "Practitioner" means:

2 (1) A physician under chapter 18.71 RCW; a physician assistant
3 under chapter 18.71A RCW; an osteopathic physician and surgeon under
4 chapter 18.57 RCW; an osteopathic physician assistant under chapter
5 18.57A RCW who is licensed under RCW 18.57A.020 subject to any
6 limitations in RCW 18.57A.040; an optometrist licensed under chapter
7 18.53 RCW who is certified by the optometry board under RCW 18.53.010
8 subject to any limitations in RCW 18.53.010; a dentist under chapter
9 18.32 RCW; a podiatric physician and surgeon under chapter 18.22 RCW;
10 a veterinarian under chapter 18.92 RCW; a registered nurse, advanced
11 registered nurse practitioner, or licensed practical nurse under
12 chapter 18.79 RCW; a naturopathic physician under chapter 18.36A RCW
13 who is licensed under RCW 18.36A.030 subject to any limitations in
14 RCW 18.36A.040; a pharmacist under chapter 18.64 RCW or a scientific
15 investigator under this chapter, licensed, registered or otherwise
16 permitted insofar as is consistent with those licensing laws to
17 distribute, dispense, conduct research with respect to or administer
18 a controlled substance in the course of their professional practice
19 or research in this state.

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

24 (3) A physician licensed to practice medicine and surgery, a
25 physician licensed to practice osteopathic medicine and surgery, a
26 dentist licensed to practice dentistry, a podiatric physician and
27 surgeon licensed to practice podiatric medicine and surgery, a
28 licensed physician assistant or a licensed osteopathic physician
29 assistant specifically approved to prescribe controlled substances by
30 his or her state's medical quality assurance commission or equivalent
31 and his or her supervising physician, an advanced registered nurse
32 practitioner licensed to prescribe controlled substances, or a
33 veterinarian licensed to practice veterinary medicine in any state of
34 the United States.

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

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

1 (mm) "Qualifying patient" has the meaning provided in RCW
2 69.51A.010.

3 (nn) "Recognition card" has the meaning provided in RCW
4 69.51A.010.

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

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

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

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

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

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

28 NEW SECTION. **Sec. 10.** Sections 1 through 7 of this act
29 constitute a new chapter in Title 69 RCW.

30 NEW SECTION. **Sec. 11.** If any provision of this act or its
31 application to any person or circumstance is held invalid, the
32 remainder of the act or the application of the provision to other
33 persons or circumstances is not affected.

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