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**BILL REQUEST - CODE REVISER'S OFFICE**

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BILL REQ. #: S-4310.1/16

ATTY/TYPIST: AR:lel

BRIEF DESCRIPTION: Concerning patients' access to investigational  
medical products.

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 physician does not commit unprofessional conduct under RCW  
7 18.130.180 and does not violate the applicable standard of care by:

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

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

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

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

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

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

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

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

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

31 Except as permitted by chapter 69.--- RCW (the new chapter  
32 created in section 11 of this act), no person shall introduce or  
33 deliver for introduction into intrastate commerce any new drug which  
34 is subject to section 505 of the federal act unless an application  
35 with respect to such drug has become effective thereunder. No person  
36 shall introduce or deliver for introduction into intrastate commerce  
37 any new drug which is not subject to section 505 of the federal act,

1 unless (1) it has been found, by appropriate tests, that such drug is  
2 not unsafe for use under the conditions prescribed, recommended, or  
3 suggested in the labeling thereof; and (2) an application has been  
4 filed under this section of this chapter with respect to such drug:  
5 PROVIDED, That the requirement of subsection (2) of this section  
6 shall not apply to any drug introduced into intrastate commerce at  
7 any time prior to the enactment of this chapter or introduced into  
8 interstate commerce at any time prior to the enactment of the federal  
9 act: PROVIDED FURTHER, That if the director finds that the  
10 requirement of subsection (2) of this section as applied to any drug  
11 or class of drugs, is not necessary for the protection of the public  
12 health, he or she shall promulgate regulations of exemption  
13 accordingly.

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

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

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

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

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

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

29 (c) "CBD concentration" has the meaning provided in RCW  
30 69.51A.010.

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

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

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

38 (i) that has a stimulant, depressant, or hallucinogenic effect on  
39 the central nervous system substantially similar to the stimulant,

1 depressant, or hallucinogenic effect on the central nervous system of  
2 a controlled substance included in Schedule I or II; or

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

9 (2) The term does not include:

10 (i) a controlled substance;

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

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

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

22 (g) "Deliver" or "delivery(( $\tau$ ))" means the actual or constructive  
23 transfer from one person to another of a substance, whether or not  
24 there is an agency relationship.

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

26 (i) "Designated provider" has the meaning provided in RCW  
27 69.51A.010.

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

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

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

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

37 (n) "Drug" means (1) a controlled substance recognized as a drug  
38 in the official United States pharmacopoeia/national formulary or the  
39 official homeopathic pharmacopoeia of the United States, or any  
40 supplement to them; (2) controlled substances intended for use in the

1 diagnosis, cure, mitigation, treatment, or prevention of disease in  
2 individuals or animals; (3) controlled substances (other than food)  
3 intended to affect the structure or any function of the body of  
4 individuals or animals; and (4) controlled substances intended for  
5 use as a component of any article specified in (1), (2), or (3) of  
6 this subsection. The term does not include devices or their  
7 components, parts, or accessories.

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

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

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

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

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

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

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

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

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

39 (u) "Manufacture" means the production, preparation, propagation,  
40 compounding, conversion, or processing of a controlled substance,

1 either directly or indirectly or by extraction from substances of  
2 natural origin, or independently by means of chemical synthesis, or  
3 by a combination of extraction and chemical synthesis, and includes  
4 any packaging or repackaging of the substance or labeling or  
5 relabeling of its container. The term does not include the  
6 preparation, compounding, packaging, repackaging, labeling, or  
7 relabeling of a controlled substance:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

36 (6) Cocaine base.

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

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

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

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

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

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

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

19 (jj) "Practitioner" means:

20 (1) A physician under chapter 18.71 RCW; a physician assistant  
21 under chapter 18.71A RCW; an osteopathic physician and surgeon under  
22 chapter 18.57 RCW; an osteopathic physician assistant under chapter  
23 18.57A RCW who is licensed under RCW 18.57A.020 subject to any  
24 limitations in RCW 18.57A.040; an optometrist licensed under chapter  
25 18.53 RCW who is certified by the optometry board under RCW 18.53.010  
26 subject to any limitations in RCW 18.53.010; a dentist under chapter  
27 18.32 RCW; a podiatric physician and surgeon under chapter 18.22 RCW;  
28 a veterinarian under chapter 18.92 RCW; a registered nurse, advanced  
29 registered nurse practitioner, or licensed practical nurse under  
30 chapter 18.79 RCW; a naturopathic physician under chapter 18.36A RCW  
31 who is licensed under RCW 18.36A.030 subject to any limitations in  
32 RCW 18.36A.040; a pharmacist under chapter 18.64 RCW or a scientific  
33 investigator under this chapter, licensed, registered or otherwise  
34 permitted insofar as is consistent with those licensing laws to  
35 distribute, dispense, conduct research with respect to or administer  
36 a controlled substance in the course of their professional practice  
37 or research in this state.

38 (2) A pharmacy, hospital or other institution licensed,  
39 registered, or otherwise permitted to distribute, dispense, conduct

1 research with respect to or to administer a controlled substance in  
2 the course of professional practice or research in this state.

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

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

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

20 (mm) "Qualifying patient" has the meaning provided in RCW  
21 69.51A.010.

22 (nn) "Recognition card" has the meaning provided in RCW  
23 69.51A.010.

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

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

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

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

39 (ss) "Ultimate user" means an individual who lawfully possesses a  
40 controlled substance for the individual's own use or for the use of a

1 member of the individual's household or for administering to an  
2 animal owned by the individual or by a member of the individual's  
3 household.

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

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

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

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