PSHB 2334

By: Representative Sawyer

SUBSTITUTE BILL MEMORANDUM

TO: Members, Commerce & Gaming Committee

FROM: Thamas Osborn, Senior Counsel

Commerce & Gaming Committee

RE: PSHB 2334 (H-3826.1)

By Representative Sawyer

DATE: January 13, 2018

Brief summary of original bill:

- Authorizes licensed marijuana producers and processors to use cannabidiol products (CBD products) obtained from sources other than state licensed producer/processors, provided such products are laboratory tested, approved by the Liquor and Cannabis Board (LCB), and meet other specified requirements.
- Requires that all CBD products used by licensed producers and processors meet legal standards for product safety and purity.
- Creates a definition of "CBD product".
- Provides the LCB with rule making authority regarding the use of CBD products by licensed marijuana producers and processors.

The proposed substitute makes the following changes to the original bill:

- Makes purely technical changes to language relating to laboratory accreditation.
- Eliminates provisions specifying certain procedural requirements for approval of a CBD product by the LCB following laboratory testing, and allows such requirements to be established by administrative rule.

- 1 AN ACT Relating to the regulation of the use of cannabinoid
- 2 additives in marijuana products; reenacting and amending RCW
- 3 69.50.101; and adding a new section to chapter 69.50 RCW.

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- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 5 <u>NEW SECTION.</u> **Sec. 1.** A new section is added to chapter 69.50 6 RCW to read as follows:
- 7 marijuana producers licensed (1)Licensed and marijuana processors may use a CBD product as an additive for the purpose of 8 enhancing the cannabidiol concentration of any product authorized for 9 10 production, processing, and sale under this chapter. Except 11 otherwise provided in subsection (2) of this section, such CBD product additives must be lawfully produced by, or purchased from, a 12 13 producer or processor licensed under this chapter.
 - (2) Subject to the requirements set forth in (a) and (b) of this subsection, and for the purpose of enhancing the cannabidiol concentration of any product authorized for production, processing, or sale under this chapter, licensed marijuana producers and licensed marijuana processors may use a CBD product obtained from a source not licensed under this chapter, provided the CBD product:
- 20 (a) Has a THC level of 0.3 percent or less on a dry weight basis; 21 and

- 1 (b) Has been tested for contaminants and toxins by a testing 2 laboratory accredited under this chapter and in accordance with 3 testing standards established under this chapter and the applicable 4 administrative rules.
- 5 (3) The liquor and cannabis board may enact rules necessary to implement the requirements of this section.
- 7 **Sec. 2.** RCW 69.50.101 and 2017 c 317 s 5, 2017 c 212 s 11, and 8 2017 c 153 s 1 are each reenacted and amended to read as follows:
- 9 The definitions in this section apply throughout this chapter 10 unless the context clearly requires otherwise.
- 11 (a) "Administer" means to apply a controlled substance, whether 12 by injection, inhalation, ingestion, or any other means, directly to 13 the body of a patient or research subject by:
- 14 (1) a practitioner authorized to prescribe (or, by the 15 practitioner's authorized agent); or
- 16 (2) the patient or research subject at the direction and in the 17 presence of the practitioner.
- 18 (b) "Agent" means an authorized person who acts on behalf of or 19 at the direction of a manufacturer, distributor, or dispenser. It 20 does not include a common or contract carrier, public 21 warehouseperson, or employee of the carrier or warehouseperson.
- 22 (c) "CBD concentration" has the meaning provided in RCW 23 69.51A.010.

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- (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, but does not include industrial hemp as defined in RCW 15.120.010.
- 29 (f)(1) "Controlled substance analog" means a substance the 30 chemical structure of which is substantially similar to the chemical 31 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 Code Rev/KB:amh

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- central nervous system of a controlled substance included in Schedule I or II.
 - (2) The term does not include:

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- (i) a controlled substance;
- 5 (ii) a substance for which there is an approved new drug 6 application;
- 7 (iii) a substance with respect to which an exemption is in effect 8 for investigational use by a particular person under Section 505 of 9 the federal food, drug, and cosmetic act, 21 U.S.C. Sec. 355, or 10 chapter 69.77 RCW to the extent conduct with respect to the substance 11 is pursuant to the exemption; or
- 12 (iv) any substance to the extent not intended for human 13 consumption before an exemption takes effect with respect to the 14 substance.
- 15 (g) "Deliver" or "delivery" means the actual or constructive 16 transfer from one person to another of a substance, whether or not 17 there is an agency relationship.
- 18 (h) "Department" means the department of health.
- 19 (i) "Designated provider" has the meaning provided in RCW 20 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.
- 27 (1) "Distribute" means to deliver other than by administering or 28 dispensing a controlled substance.
 - (m) "Distributor" means a person who distributes.

components, parts, or accessories.

(n) "Drug" means (1) a controlled substance recognized as a drug 30 31 in the official United States pharmacopoeia/national formulary or the official homeopathic pharmacopoeia of the United States, or any 32 supplement to them; (2) controlled substances intended for use in the 33 diagnosis, cure, mitigation, treatment, or prevention of disease in 34 individuals or animals; (3) controlled substances (other than food) 35 36 intended to affect the structure or any function of the body of individuals or animals; and (4) controlled substances intended for 37 use as a component of any article specified in (1), (2), or (3) of 38 39 this subsection. The term does not include devices or their

- 1 (o) "Drug enforcement administration" means the drug enforcement 2 administration in the United States Department of Justice, or its 3 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.
- 9 (q) "Immature plant or clone" means a plant or clone that has no 10 flowers, is less than twelve inches in height, and is less than 11 twelve inches in diameter.
 - (r) "Immediate precursor" means a substance:

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- 13 (1) that the commission has found to be and by rule designates as 14 being the principal compound commonly used, or produced primarily for 15 use, in the manufacture of a controlled substance;
- 16 (2) that is an immediate chemical intermediary used or likely to 17 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.
 - (s) "Isomer" means an optical isomer, but in subsection (ee)(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.
 - (t) "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.
 - (u) "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.
- (v) "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 Code Rev/KB:amh

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- 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.
 - (w) "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:
 - (1) 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; or
 - (2) Industrial hemp as defined in RCW 15.120.010.
 - (x) "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.
 - (y) "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.
 - (z) "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.
- 37 (aa) "Marijuana products" means useable marijuana, marijuana 38 concentrates, and marijuana-infused products as defined in this 39 section.

- 1 (bb) "Marijuana researcher" means a person licensed by the state 2 liquor and cannabis board to produce, process, and possess marijuana 3 for the purposes of conducting research on marijuana and marijuana-4 derived drug products.
- 5 (cc) "Marijuana retailer" means a person licensed by the state 6 liquor and cannabis board to sell marijuana concentrates, useable 7 marijuana, and marijuana-infused products in a retail outlet.
 - (dd) "Marijuana-infused products" means products that contain marijuana or marijuana extracts, are intended for human use, are derived from marijuana as defined in subsection (w) 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.
 - (ee) "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.
- 29 (4) Coca leaves, except coca leaves and extracts of coca leaves 30 from which cocaine, ecgonine, and derivatives or ecgonine or their 31 salts have been removed.
 - (5) Cocaine, or any salt, isomer, or salt of isomer thereof.
 - (6) Cocaine base.

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- 34 (7) Ecgonine, or any derivative, salt, isomer, or salt of isomer 35 thereof.
- 36 (8) Any compound, mixture, or preparation containing any quantity 37 of any substance referred to in subparagraphs (1) through (7).
- (ff) "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-Code Rev/KB:amh

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- 1 sustaining liability. The term includes opium, substances derived
- 2 from opium (opium derivatives), and synthetic opiates. The term does
- 3 not include, unless specifically designated as controlled under RCW
- 4 69.50.201, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan
- 5 and its salts (dextromethorphan). The term includes the racemic and
- 6 levorotatory forms of dextromethorphan.
- 7 (gg) "Opium poppy" means the plant of the species Papaver 8 somniferum L., except its seeds.
- 9 (hh) "Person" means individual, corporation, business trust, 10 estate, trust, partnership, association, joint venture, government, 11 governmental subdivision or agency, or any other legal or commercial
- 12 entity.

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- (ii) "Plant" has the meaning provided in RCW 69.51A.010.
- 14 (jj) "Poppy straw" means all parts, except the seeds, of the 15 opium poppy, after mowing.
 - (kk) "Practitioner" means:
- 17 (1) A physician under chapter 18.71 RCW; a physician assistant under chapter 18.71A RCW; an osteopathic physician and surgeon under 18 19 chapter 18.57 RCW; an osteopathic physician assistant under chapter 18.57A RCW who is licensed under RCW 18.57A.020 subject to any 20 21 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 22 subject to any limitations in RCW 18.53.010; a dentist under chapter 23 24 18.32 RCW; a podiatric physician and surgeon under chapter 18.22 RCW; 25 a veterinarian under chapter 18.92 RCW; a registered nurse, advanced registered nurse practitioner, or licensed practical nurse under 26 chapter 18.79 RCW; a naturopathic physician under chapter 18.36A RCW 27 28 who is licensed under RCW 18.36A.030 subject to any limitations in 29 RCW 18.36A.040; a pharmacist under chapter 18.64 RCW or a scientific investigator under this chapter, licensed, registered or otherwise 30 31 permitted insofar as is consistent with those licensing laws to distribute, dispense, conduct research with respect to or administer 32 a controlled substance in the course of their professional practice 33 or research in this state. 34
 - (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.
- 39 (3) A physician licensed to practice medicine and surgery, a 40 physician licensed to practice osteopathic medicine and surgery, a Code Rev/KB:amh
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- 1 dentist licensed to practice dentistry, a podiatric physician and
- 2 surgeon licensed to practice podiatric medicine and surgery, a
- 3 licensed physician assistant or a licensed osteopathic physician
- 4 assistant specifically approved to prescribe controlled substances by
- 5 his or her state's medical quality assurance commission or equivalent
- 6 and his or her supervising physician, an advanced registered nurse
- 7 practitioner licensed to prescribe controlled substances, or a
- 8 veterinarian licensed to practice veterinary medicine in any state of
- 9 the United States.
- 10 (11) "Prescription" means an order for controlled substances 11 issued by a practitioner duly authorized by law or rule in the state 12 of Washington to prescribe controlled substances within the scope of
- 13 his or her professional practice for a legitimate medical purpose.
- 14 (mm) "Production" includes the manufacturing, planting, 15 cultivating, growing, or harvesting of a controlled substance.
- 16 (nn) "Qualifying patient" has the meaning provided in RCW 17 69.51A.010.
- 18 (oo) "Recognition card" has the meaning provided in RCW 19 69.51A.010.
- (pp) "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.
- 23 (qq) "Secretary" means the secretary of health or the secretary's designee.
- (rr) "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.
 - (ss) "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.
- 35 (tt) "Ultimate user" means an individual who lawfully possesses a 36 controlled substance for the individual's own use or for the use of a 37 member of the individual's household or for administering to an 38 animal owned by the individual or by a member of the individual's 39 household.

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- 1 (uu) "Useable marijuana" means dried marijuana flowers. The term 2 "useable marijuana" does not include either marijuana-infused 3 products or marijuana concentrates.
 - (vv) "CBD product" means any product containing or consisting of cannabidiol.

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