Chapter 246-70 WAC MARIJUANA PRODUCT COMPLIANCE

NEW SECTION

WAC 246-70-010 Findings. Anecdotal and limited scientific evidence indicates that the use of marijuana may be beneficial to alleviate the symptoms of certain physical and mental conditions. However, due to the current federal classification of marijuana as a schedule 1 controlled substance, scientific research has not been performed that would allow for standardized indications of particular strains, which can vary radically in cannabinoid composition; standard, reproducible formula or dosage; or accepted standards for drug purity, potency and quality for the various conditions for which the medical use of marijuana may be authorized. At this time, the decision of what marijuana products may be beneficial is best made by patients in consultation with their health care practitioners. For this reason, the department will not limit the types of products available to qualifying patients. Instead, the department intends to create standards for products that any consumer can rely upon to be reasonably safe and meet quality assurance measures.

NEW SECTION

WAC 246-70-020 Applicability of WSLCB rules. The requirements in this chapter are in addition to all WSLCB requirements in chapter 314-55 WAC. They are intended to build upon all other requirements for licensed marijuana producers, processors and retailers, and certified third-party labs.

NEW SECTION

- WAC 246-70-030 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.
- (1) "Allowed pesticide" means a pesticide registered by the Washington state department of agriculture under chapter 15.58 RCW as allowed for use in the production, processing, and handling of marijuana.
- (2) "Batch" means a quantity of marijuana-infused product containing material from one or more lots of marijuana.
- (3) "CBD concentration" means the percent of cannabidiol content per dry weight of any part of the plant *Cannabis*, or per volume or weight of marijuana product.
- (4) "Certified third-party testing lab" means a laboratory certified by the WSLCB or its vendor under WAC 314-55-102.

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- (5) "Data base" means the medical marijuana authorization data base created pursuant to RCW 69.51A.230.
 - (6) "Department" means the Washington state department of health.
- (7) "Designated provider" has the same meaning as RCW 69.51A. 010(4).
- (8) "Harvest" means the marijuana plant material derived from plants of the same strain that were brought into cultivation at the same time, grown in the same manner and physical space, and gathered at the same time.
- (9) "Imported cannabinoid" means any cannabinoid derived of the plant *Cannabis* with a THC concentration 0.3 percent or less that is not produced by a licensed marijuana producer.
 - (10) "Lot" means either of the following:
- (a) The flowers from one or more marijuana plant(s) of the same strain. A single lot of flowers cannot weigh more than five pounds; or
- (b) The trim, leaves, or other plant matter from one or more marijuana plant(s). A single lot of trim, leaves, or other plant matter cannot weigh more than fifteen pounds.
- (11) "Marijuana" means all parts of the plant Cannabis, whether growing or not, with a THC concentration greater than 0.3 percent on a dry weight basis; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.
- (12) "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.
- (13) "Marijuana-infused products" means products that contain marijuana or marijuana extracts, are intended for human use, are derived from marijuana as defined in subsection (11) of this section, and have a THC concentration no greater than ten percent. The term "marijuana-infused products" does not include either usable marijuana or marijuana concentrates.
- (14) "Marijuana processor" means a person licensed by the WSLCB under RCW 69.50.325 to process marijuana into marijuana concentrates, usable marijuana and marijuana-infused products, package and label marijuana concentrates, usable marijuana and marijuana-infused products for sale in retail outlets, and sell marijuana concentrates, usable marijuana and marijuana-infused products at wholesale to marijuana retailers.
- (15) "Marijuana producer" means a person licensed by the WSLCB under RCW 69.50.325 to produce and sell marijuana at wholesale to marijuana processors and other marijuana producers.
- (16) "Marijuana product" means marijuana, marijuana concentrates, usable marijuana, and marijuana-infused products as defined in this section.
- (17) "Medical use of marijuana" has the same meaning as RCW 69.51A.010(3).
 - (18) "Plant" means a marijuana plant.
- (19) "Production" includes the manufacturing, planting, cultivating, growing, or harvesting of marijuana.

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- (20) "Qualifying patient" or "patient" has the same meaning as RCW 69.51A.010(19).
- (21) "Pesticide" means, but is not limited to: (a) Any substance or mixture of substances intended to prevent, destroy, control, repel, or mitigate any insect, rodent, snail, slug, fungus, weed, and any other form of plant or animal life or virus, except virus on or in a living person or other animal which is normally considered to be a pest; (b) any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; and (c) any spray adjuvant. Pesticides include substances commonly referred to as herbicides, fungicides, insecticides, and cloning agents.
- (22) "Recognition card" means a card issued to qualifying patients and designated providers by a marijuana retailer with a medical marijuana endorsement that has entered them into the medical marijuana data base.
- (23) "Retail outlet" means a location licensed by the WSLCB under RCW 69.50.325 for the retail sale of usable marijuana and marijuana-infused products.
- (24) "Retail outlet with a medical marijuana endorsement" means a location licensed by the WSLCB under RCW 69.50.325 for the retail sale of marijuana products to the public and, under RCW 69.50.375, to qualifying patients and designated providers for medical use.
- (25) "Secretary" means the secretary of the department of health or the secretary's designee.
- (26) "THC concentration" means the 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.
- (27) "Tincture" means a solution containing marijuana extract. A single unit of tincture cannot exceed two fluid ounces.
- (28) "Topical product" means a product intended for use only as an application to human body surfaces, does not cross the blood-brain barrier, and is not meant to be ingested by humans or animals.
- (29) "Unit" means an individually packaged marijuana product containing up to ten servings or applications. (30) "Usable marijuana" means dried marijuana flowers. The term
- (30) "Usable marijuana" means dried marijuana flowers. The term "usable marijuana" does not include either marijuana-infused products or marijuana concentrates.
- (31) "WSLCB" means the Washington state liquor and cannabis board.

NEW SECTION

- WAC 246-70-040 Marijuana products compliant with this chapter. To be classified as a compliant marijuana product, the product must meet all requirements of this chapter. Compliant marijuana products must fall into one of the following classifications:
 - (1) General use.
- (a) "General use compliant product" means any marijuana product approved by the WSLCB, including edibles, and meeting the requirements of this chapter.
- (b) General use marijuana-infused compliant products may be packaged in servings or applications containing up to ten milligrams of

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active THC. A unit must not contain more than ten servings or applications and must not exceed one hundred total milligrams of active THC.

- (c) General use compliant products must be labeled "Chapter 246-70 WAC, Compliant—General Use" and must use the logo developed and approved by the department to indicate compliance with this chapter.
- (d) General use compliant products may be purchased by any adult age twenty-one or older, and qualifying patients between the ages of eighteen and twenty who are entered into the data base and hold a valid recognition card.
- (e) General use compliant products may be sold at retail outlets and retail outlets with a medical marijuana endorsement.
 - (2) High THC.
- (a) "High THC compliant product" means a marijuana product containing more than ten but no more than fifty milligrams of THC per serving or application and meeting the requirements of this chapter.
- (b) The following is an exclusive list of marijuana products that may qualify for classification as a high THC compliant product:
 - (i) Capsules;
 - (ii) Tinctures;
 - (iii) Transdermal patches; and
 - (iv) Suppositories.
- (c) No other marijuana products can be classified as a high THC compliant product or contain more than ten milligrams of active THC per serving or application.
- (d) High THC compliant products may be packaged in servings or applications containing up to fifty milligrams of active THC. A unit must not contain more than ten servings or applications and must not exceed five hundred total milligrams of active THC.
- (e) High THC compliant products must be labeled "Chapter 246-70 WAC Compliant High THC" and must use the logo developed and approved by the department to indicate compliance with this chapter.
- (f) High THC compliant products may be purchased only by qualifying patients age eighteen and older and designated providers who are entered into the data base and hold a valid recognition card.
- (g) High THC compliant products may be sold only at retail outlets with a medical marijuana endorsement.
 - (3) High CBD.
- (a) "High CBD compliant product" means any marijuana product, except usable marijuana or other plant material intended for smoking, approved by the WSLCB, including edibles, meeting the requirements of this chapter and containing the following ratios:
- (i) Marijuana extracts containing not more than two percent THC concentration and at least twenty-five times more CBD concentration by weight.
- (ii) Marijuana-infused edible products containing not more than two milligrams of active THC and at least five times more CBD per serving by weight for solids or volume for liquids.
- (iii) Marijuana-infused topical products containing at least five times more CBD concentration than THC concentration.
- (b) High CBD compliant products must be labeled "Chapter 246-70 WAC Compliant High CBD" and must use the logo developed and approved by the department to indicate compliance with this chapter.
- (c) High CBD compliant products may be purchased by any adult age twenty-one or older, and qualifying patients between the ages of

eighteen and twenty who are entered into the data base and hold a valid recognition card.

(d) High CBD compliant products may be sold at retail outlets and retail outlets with a medical marijuana endorsement.

NEW SECTION

- WAC 246-70-050 Quality assurance testing. (1) Testing. In addition to the tests required under WAC 314-55-102, the following tests shall be performed at the intervals indicated by a third-party testing lab certified by the WSLCB:
- (a) Pesticide screening and heavy metal screening are required at the time of harvest for all marijuana flowers, trim, leaves, or other plant matter.
- (i) Minimum sample size is three grams for every three pounds of harvested product.
- (ii) Harvest amounts will be rounded up to the next three-pound interval. For example, a harvest of less than three pounds requires at least three grams for testing; a harvest of three or more pounds but less than six pounds requires at least six grams for testing.
- (b) Mycotoxin screening is required whenever microbial testing for any marijuana product is required by the WSLCB.
- (c) In addition to the pesticide screening required in subsection
 (1)(a) of this section, additional pesticide screening is required
 for:
 - (i) Each batch of finished concentrates and extracts; and
- (ii) Any imported cannabinoid intended for use in a marijuana product.

The minimum sample size for each batch of finished concentrates and extracts is two grams. The sample size for imported cannabinoids is one percent of the product as packaged by the manufacturer of the imported cannabinoid but in no case shall the sample be less than two grams.

- (d) In addition to the heavy metal screening required in (a) of this subsection, additional heavy metal screening is required for any imported cannabinoid intended for use in a marijuana product. The sample size for imported cannabinoids is one percent of the product as packaged by the manufacturer of the imported cannabinoid but in no case shall the sample be less than two grams.
- (e) Licensed marijuana producers, licensed marijuana processors, and certified third-party labs must follow the sampling protocols in chapter $314-55\ \text{WAC}$.
 - (2) Pesticide screening.
- (a) Only allowed pesticides shall be used in the production, processing, and handling of marijuana. Pesticide use must be consistent with the manufacturer's label requirements.
- (b) Certified third-party labs must screen for any pesticides that are not allowed and are designated as having the potential for misuse on a list created, maintained, and periodically updated by the department in consultation with the Washington state department of agriculture and the WSLCB. Certified third-party labs must also screen for pyrethrins and piperonyl butoxide (PBO) in samples of finished concentrates and extracts.
 - (c) For purposes of the pesticide screening:

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- (i) A sample of any marijuana product shall be deemed to have failed if a pesticide that is not allowed is detected in any measurable and positively verified amount.
- (ii) A sample of finished concentrate or extract shall be deemed to have failed if more than 1.0 ppm of allowed pyrethrins or 2.0 ppm of piperonyl butoxide (PBO) is detected.
- (d) A harvest or batch deemed to have failed pesticide screening must be destroyed. Marijuana flowers, trim, leaves, or other plant matter deemed to have failed pesticide screening must not be used to create extracts or concentrates. Imported cannabinoids deemed to have failed pesticide screening must not be added to any marijuana product.
- (e) Pesticides containing allowed pyrethrins or piperonyl butoxide (PBO) may not be applied less than seven days prior to harvest.
- (f) All individuals applying pesticides shall adhere to the agricultural use requirements on the label. Pesticide applications that do not follow the pesticide product label may pose risks to public health and safety and are a violation of chapter 15.58 RCW.
 - (3) Heavy metal screening.
- (a) For the purposes of heavy metal screening, a sample shall be deemed to have passed if it meets the following standards:

Metal	Limit, µg/daily dose (5 grams)
Inorganic arsenic	 10.0
Cadmium	 4.1
Lead	 6.0
Mercury	 2.0

- (b) A harvest deemed to have failed heavy metal screening must be destroyed. Marijuana flowers, trim, leaves, or other plant matter deemed to have failed heavy metal screening must not be used to create extracts or concentrates. Imported cannabinoids deemed to have failed heavy metal screening must not be added to any marijuana product.
- (4) For purposes of mycotoxin screening, a sample shall be deemed to have passed if it meets the following standards:

Test	Specification
The total of aflatoxin B1, aflatoxin B2, aflatoxin G1	
and aflatoxin G2	<20 μG/kg of substance
Ochratoxin A	<20 μG/kg of substance

- (5) Terpenes.
- (a) Terpene analysis is not required. If terpene content is listed on product packaging or label, a terpene analysis from a certified third-party lab must be available for review by the consumer upon request.
- (b) The addition of any terpene to useable marijuana is prohibited. Only the following terpenes may be added to a marijuana product other than useable marijuana.
 - (i) Terpenes naturally occurring in marijuana; or
- (ii) Terpenes permitted or generally recognized as safe by, and used in accordance with, 21 C.F.R., Chapter I, subchapter B.

NEW SECTION

- WAC 246-70-060 Compliant product labeling. (1) Products meeting the requirements of this chapter must be readily identifiable to the consumer by placement on the product's label of the logo developed and approved by the department.
 - (2) Labels for compliant products must not:
- (a) Use any word(s), symbol, or image commonly used in or by medical or pharmaceutical professions including, but not limited to: Depiction of a caduceus, staff of Asclepius, bowl of Hygieia, or mortar and pestle; or use of the word "prescription" or letters "RX";
- (b) State or imply any specific medical or therapeutic benefit; or
 - (c) Mimic a brand of over-the-counter or legend drug.
- (3) The label must prominently display the following statement: "This product is not approved by the FDA to treat, cure, or prevent any disease."
- (4) Marijuana products that use the logo developed and approved by the department but do not meet the requirements in this chapter will be reported to the WSLCB.

NEW SECTION

- WAC 246-70-070 Compliant product safe handling. (1) Marijuana processors shall ensure all processing facilities that create or handle marijuana-infused products are constructed, kept, and maintained in a clean and sanitary condition in accordance with rules as prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.
- (2) Marijuana processors that do not create or handle marijuana-infused products and all marijuana producers shall adopt and enforce policies and procedures to ensure that operations involving the growing, receiving, inspecting, transporting, segregating, preparing, production, packaging, and storing of marijuana or marijuana products are conducted in accordance with adequate sanitation principles including:
- (a) Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with marijuana, marijuana plants, or marijuana products shall be excluded from any operations that may be expected to result in microbial contamination until the condition is corrected.
- (b) Hand-washing facilities must be available and furnished with running water. Hand-washing facilities shall be located in the permitted premises and where good sanitary practices require employees to wash or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices.
- (c) All persons working in direct contact with marijuana, marijuana plants, or marijuana products must conform to hygienic practices while on duty including, but not limited to:
 - (i) Maintaining personal cleanliness;

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- (ii) Washing hands thoroughly in hand-washing areas before starting work and at any other time when the hands may have become soiled or contaminated;
- (iii) Refraining from having direct contact with marijuana, marijuana plants, or marijuana products if the person has or may have an illness, open lesion, including boils, sores or infected wounds, or any other abnormal source of microbial contamination, until the condition is corrected.
- (d) Litter and waste are properly removed and the operating systems for waste disposal are maintained in a manner so that they do not constitute a source of contamination in areas where marijuana, marijuana plants, or marijuana products may be exposed.
- (e) Floors, walls and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and in good repair.(f) There is adequate lighting in all areas where marijuana, mar-
- (f) There is adequate lighting in all areas where marijuana, marijuana plants, or marijuana products are stored and where equipment or utensils are cleaned.
- (g) There is adequate screening or other protection against the entry of pests. Rubbish must be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests.
- (h) Any buildings, fixtures, and other facilities are maintained in a sanitary condition.
- (i) Toxic cleaning compounds, sanitizing agents, and solvents used in the production of marijuana concentrates must be identified, held and stored in a manner that protects against contamination of marijuana, marijuana plants, and marijuana products, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation, or ordinance.
- (j) All contact surfaces, including utensils and equipment used for the preparation of marijuana, marijuana plants, or marijuana products must be cleaned and sanitized regularly to protect against contamination. Equipment and utensils must be designed and be of such material and workmanship as to be adequately cleanable, and must be properly maintained. Sanitizing agents must be used in accordance with labeled instructions.
- (k) The water supply must be sufficient for the operations and capable of providing a safe, potable, and adequate supply of water to meet the facility's needs. Each facility must provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair.

NEW SECTION

- WAC 246-70-080 Employee training. (1) Marijuana producers, processors and retailers that create, handle, or sell compliant marijuana products shall adopt and enforce policies and procedures to ensure employees and volunteers receive training about the requirements of this chapter.
- (2) Marijuana retailers holding a medical marijuana endorsement shall also adopt and enforce policies and procedures to ensure employees and volunteers receive training about:

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- (a) Procedures regarding the recognition of valid authorizations and the use of equipment to enter qualifying patients and designated providers into the medical marijuana authorization data base;
 - (b) Identification of valid recognition cards;
 - (c) Adherence to confidentiality requirements; and
- (d) Science-based information about cannabinoids, strains, varieties, THC concentration, CBD concentration, and THC to CBD ratios of marijuana concentrates, usable marijuana, and marijuana-infused products available for sale when assisting qualifying patients and designated providers at the retail outlet.
- (3) Nothing in subsection (2) of this section allows any owner, employee, or volunteer to:
- (a) Perform the duties of a medical marijuana consultant or represent themselves as a medical marijuana consultant unless the person holds a valid certificate issued by the secretary under chapter 246-72 WAC;
- (b) Offer or undertake to diagnose or cure any human or animal disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, by use of marijuana products or any other means or instrumentality; or
- (c) Recommend or suggest modification or elimination of any course of treatment that does not involve the medical use of marijuana or marijuana products.

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