



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health

- Preproposal Statement of Inquiry was filed as WSR 15-20-081 ; or
- Expedited Rule Making--Proposed notice was filed as WSR ; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

Chapter 246-70 WAC - Marijuana Product Compliance. Proposing a new chapter regarding rules for marijuana products beneficial for medical use including product categories, quality assurance testing (pesticide, mycotoxin, heavy metal, terpenes), product labeling, safe handling, and employee training standards.

Hearing location(s): See Attachment 1

Submit written comments to:

Name: Susan Reynolds
Address: PO Box 47852
Olympia, WA 98504-7852
e-mail: <https://fortress.wa.gov/doh/policyreview/>
fax 360-236-2901 by (date) 03/25/2016

Date: See Attach. 1 Time: See Attach.1

Assistance for persons with disabilities: Contact

Susan Reynolds by dates on Attachment 1

TTY (800) 833-6388 or () 711

Date of intended adoption: 04/01/2016

(Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

To establish requirements for marijuana products beneficial for medical use by qualifying patients, quality assurance testing (pesticide, mycotoxin, heavy metal, terpenes), product labeling, safe handling, and employee training standards.

Reasons supporting proposal:

Rule making by the Department of Health is mandated by statute to establish standards for products that are beneficial for medical use. Such rules will be key to the process to produce, process, and make available an adequate supply of regulated marijuana products by July 1, 2016.

Statutory authority for adoption:

RCW 69.50.375

Statute being implemented:

RCW 69.50.375 and 82.08.9998

Is rule necessary because of a:

- Federal Law? Yes No
- Federal Court Decision? Yes No
- State Court Decision? Yes No

If yes, CITATION:

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE 02/16/2016

NAME (type or print)

John Wiesman, DrPH, MPH

SIGNATURE

, Dr.PH. MPH

TITLE

Secretary of Health

DATE: February 16, 2016

TIME: 11:02 AM

WSR 16-05-079

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None

Name of proponent: (person or organization) Department of Health

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Kristi Weeks	101 Israel RD SE Tumwater, WA 98501	360-236-4066
Implementation.... Chris Baumgartner	111 Israel Rd SE Tumwater, WA 98501	360-236-4819
Enforcement..... Chris Baumgartner	111 Israel Rd SE Tumwater, WA 98501	360-236-4819

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name: Susan Reynolds

Address: PO Box 47852
Olympia, WA 98504-7852

phone 360-236-4819

fax 360-236-2901

e-mail medicalmarijuana@doh.wa.gov

No. Explain why no statement was prepared.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Susan Reynolds

Address: PO Box 47852
Olympia, WA 98504-7852

phone 360-236-4819

fax 360-236-2901

e-mail medicalmarijuana@doh.wa.gov

No: Please explain:

**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.

- (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(16).
- (18) "Plant" means a marijuana plant.
- (19) "Production" includes the manufacturing, planting, cultivating, growing, or harvesting of marijuana.

(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 "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

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 found in WAC 246-70-090 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 found in WAC 246-70-090 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 found in WAC 246-70-090 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 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:

(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 appropriate logo found in WAC 246-70-090. A logo must be used in compliance with this chapter and any guidance for use developed by the department. A logo may not be used on any object or merchandise other than a compliant marijuana product. A logo used in accordance with this chapter must be printed in either black or dark blue.

(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) Only marijuana products complying with this chapter may use a logo found in WAC 246-70-090. Marijuana products that use a logo 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;

(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, 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:

(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.

NEW SECTION

WAC 246-70-090 Marijuana product compliant logos.





Attachment 1

Proposed Rule Making (CR-102)

Chapter 246-70 WAC – Marijuana Product Compliance: Proposing a new chapter establishing rules for marijuana products beneficial for medical use including product categories, quality assurance testing (e.g. pesticides, mycotoxins, heavy metals, terpenes), product labeling, safe handling, and employee training standards.

Notice of Public Hearings

The Department of Health (department) will conduct two public hearings for this rule proposal. Written comments may be submitted to the department at any time up until the second public hearing on March 25, 2016. Further information regarding how and where to send written public comments or make hearing arrangements for those with disabilities may be found on the CR-102 form.

Public Hearing #1

Date: March 22, 2016
Time: 10:00am
Location: Red Lion Hotel at the Park (Ballroom A)
303 W. North River Drive
Spokane, WA 99201

Assistance for persons with disabilities must be arranged with the department by March 15th, 2016.

Public Hearing #2

Date: March 25, 2016
Time: 9:00am
Location: Capital Event Center at ESD 113 (Pacific/Grays Harbor Room)
6005 Tye Drive SW
Tumwater, WA 98512

Assistance for persons with disabilities must be arranged with the department by March 18th, 2016.

Small Business Economic Impact Statement
Chapter 246-70 WAC
A Rule Concerning Medical Marijuana Product Compliance
January 11, 2016

Describe the proposed rule, including: a brief history of the issue; an explanation of why the proposed rule is needed; and a brief description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The Washington State Department of Health (department) is proposing a new chapter in rule that would create standards for marijuana products that any consumer can rely upon to be reasonably safe and meet quality assurance measures.

The proposed rule is one piece of the overall implementation of medical marijuana and is required by Second Substitute Senate Bill 5052 (Chapter 70, Laws of 2015, Regular Session) and Second Engrossed Second Substitute House Bill 2136 (Chapter 4, laws of 2015, 2nd Special Session). The purpose of the product compliance standards is to establish requirements for products that may be beneficial for medical use by qualifying patients, quality assurance testing (pesticides, mycotoxins, heavy metals), product labeling, and safe handling standards.

On April 24, 2015, Governor Inslee signed 2SSB 5052, the Cannabis Patient Protection Act. This act creates licensing and regulation of all marijuana producers, processors and retail stores under the oversight of the renamed Washington State Liquor and Cannabis Board (WSLCB). It also directs the Department of Health to complete tasks that include:

- Contracting with a third party to create and administer a medical marijuana authorization database
- Adopting rules relating to the operation of the database
- Adopting rules regarding products sold to patients and their designated providers
- Consulting with the WSLCB about requirements for a retail store to get a medical marijuana endorsement
- Creating a medical marijuana consultant certification program
- Developing and approving continuing education for healthcare practitioners who authorize the medical use of marijuana
- Making recommendations to the legislature about establishing medical marijuana specialty clinics

On June 30, 2015, Governor Inslee signed 2ESSHB 2136 which included a requirement for the department to establish in rule a tetrahydrocannabinol (THC) and cannabidiol (CBD) ratios for products that can be sold sales tax free to any adult.

The proposed rules collectively create compliance standards for marijuana products available to qualifying patients, designated providers, and other consumers.

The requirements that a small business must follow to comply with the proposed rule are found in the following sections:

- WAC 246-70-040 - Marijuana products compliant with this chapter
- WAC 246-70-050 - Quality assurance testing
- WAC 246-70-060 - Compliant product labeling
- WAC 246-70-070 - Compliant product safe handling
- WAC 246-70-080 - Employee training

In order to comply with the proposed rules, small business such as licensed marijuana producers and processors will use the services of one or more certified third-party testing labs to provide required compliant product testing in accordance with WAC 246-70-050, in addition to the tests already required under LCB rule (WAC 314-55-102).

Background

The department requested stakeholders to provide feedback on the potential cost to implement the proposed changes through four public stakeholder meetings, written feedback and survey response. Through this stakeholder input, the department determined that the collective cost of the rule changes are nominal. More detailed cost estimates are included in the sections below.

Identify which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS) codes and what the minor cost thresholds are.

There are no NAICS codes for the businesses so the minor cost threshold could not be determined. The businesses that are required to comply with the proposed rule are:

Business Description	# of businesses in WA	Estimated Average Annual Receipts
Licensed marijuana retail stores*	197	\$259,785,729
Licensed marijuana producers and processors	160 producer only licenses, 560 producer/processor licenses, and 84 processor only licenses	\$17,719,649.00
WSLCB-certified testing laboratories.	12	\$757,732 (based on average cost for testing and number of tests conducted in 2015)

*The WSLCB is currently accepting applications for new retail stores. This number could eventually be as high as 556.

Analyze the probable cost of compliance. Identify the probable costs to comply with the proposed rule, including: cost of equipment, supplies, labor, professional services and

increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or review.

Table: Rule Sections that will not likely result in cost:

#	WAC Section	Section Title
1	WAC-246-70-010	Findings
2	WAC-246-70-020	Applicability of WSLCB rules
3	WAC-246-70-030	Definitions
4	WAC-246-070-090	Marijuana product compliant logos

The department analyzed the cost of compliance to the proposed rules:

**WAC 246-70-040 Marijuana products compliant with this chapter
WAC 246-70-060 Compliant product labeling**

Description of the proposed rule: The proposed rules establish the requirements for a marijuana product to be classified as compliant. The proposed rule also establishes the labeling requirements for compliant marijuana products. The products must be readily identifiable to the consumer by placement on the product's label of the logo in proposed WAC 246-70-090 (section -090 is a rendering of the logo only). Compliant marijuana products must fall into one of the following classifications:

- General use
- High THC
- High CBD

Compliant marijuana products must be labeled in accordance with this chapter, and must use the logo developed and approved by the department to indicate compliance. The proposed rule also identifies what cannot be placed on labels of compliant products.

Compliance costs:

The proposed rules state the compliance requirements for identifying three categories of marijuana products and labeling requirements for the products, using a logo in proposed WAC 246-70-090. The logo is provided free to processors, so the labeling cost is minimal. Processors may choose to add the logo as part of their existing product packaging incurring a one-time cost, or have labels pre-printed by an outside vendor for an estimated cost of \$44.80 per five pound lot of tested marijuana, assuming each lot is placed into one gram packages for retail sale. The total cost of labeling is indeterminate because it is unknown how many lots of product may be produced by each business and how the raw marijuana will be further processed and packaged.

WAC 246-70-050 Quality assurance testing

Description of the proposed rule: The proposed rule establishes the requirements for testing performed by a third-party testing lab certified by the WSLCB. Licensed marijuana producers and processors, and third party labs must follow the sampling protocols in WSLCB rules (chapter 314-55 WAC). The following tests are in addition to the tests required under WAC 314-55-102:

- Pesticide screening and heavy metal screening is required at time of harvest for all marijuana flowers, trim, leaves, or other plant matter.
- Mycotoxin screening is required whenever microbial testing for any marijuana product is required by the WSLCB.
- Additional pesticide screening is required for each batch of finished concentrates and extracts.
- Additional pesticide and heavy metal screening is required for all imported cannabinoids, such as CBD oil, prior to addition to a marijuana product.

Compliance costs:

The proposed rule establishes requirements for marijuana product testing to be performed by a third-party testing lab certified by the WSLCB. Equipment costs for certified third-party testing labs vary, according to the type of testing performed, and the brand and age of equipment purchased by the lab. Marijuana producers and processors would incur testing costs based on the type of testing performed, the volume of product tested, and any retesting required. Results of a survey of certified testing labs showed the range of costs per test to be:

- Pesticide screening: \$100-\$350
- Heavy metals screening: \$85-\$350
- Mycotoxin testing: \$25-\$350

The market for laboratory testing is highly competitive. It is likely the labs will price their testing as low as possible in order to attract business from the limited number of producers and processors. In addition, an established laboratory in Nevada, where these tests are currently required, charges \$100 each for pesticide and heavy metals screening.

The total compliance test costs are estimated to be \$757,732.50 or approximately four percent of producer and processor total sales.

Results of a survey of certified testing labs returned the following average one-time equipment costs:

- Pesticide screening - \$325,000
- Heavy metal screening - \$255,000
- Mycotoxin screening - \$12,000
- Fume hood (additional) - \$160,000
- The number of WSLCB-required tests performed from December 1, 2014 to November 30, 2015 was 43,300. A total of fourteen certified labs performed the tests (note: there are currently only 12 labs operating). There are some current third-party certified testing labs that have equipment in place to perform the required product testing; new testing labs would incur one-time equipment costs

at startup. The costs of additional testing equipment would be based on the useful life of the equipment, i.e., the annual costs of heavy metal screening with 10 year useful life is \$25,500.

WAC 246-70-070 Compliant product safe handling

Description of the proposed rule: The proposed rule establishes the requirements for marijuana processors that create or handle marijuana –infused products to ensure products are constructed, kept, and maintained in a clean and sanitary condition. These requirements are in accordance with rules as prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.

The proposed rule also requires those marijuana processors that do not create or handle marijuana –infused product; and all marijuana producers to 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.

Cost of Compliance: The proposed rule sets requirements for all marijuana processing facilities to ensure the facility operations are conducted in accordance with adequate sanitation and safe-handling principles, based on policies and procedures created and enforced by the processor business. The cost to the businesses would be administrative work to develop and enforce policies and procedures for safe handling of marijuana products. Many of these requirements may already be in place based on requirements from other regulatory entities such as the Department of Labor and Industries.

WAC 246-70-080 Employee training

Description of the proposed rule: The proposed rule establishes requirements for marijuana producers, processors and retailers that create, handle, or sell compliant marijuana products to adopt and enforce policies and procedures to ensure employees and volunteers receive training about the requirements of this chapter. The proposed rule also establishes the activities that any retail outlet owner, employee, or volunteer is not allowed to do when assisting qualifying patients and designated providers at the retail outlet.

Compliance costs:

The proposed rule states the requirements for employee training by marijuana producers, processors and retailers on this chapter. On the job training for employees will vary based on the duties they perform and the material presented. The average time to become trained in the requirements of this chapter is estimated to be 2 hours total. Based on survey results of retail stores showing the employee average wage to be \$22.00 an hour, the result would be a one-time training cost of \$44.00 per employee. This estimated cost is low and should not affect sales or revenue.

Analyze whether compliance with the proposed rule will cause businesses to lose sales or revenue.

The proposed rule are not anticipated to cause any business to lose sales or revenue. Compliance will help authorized retail outlets to identify for customers which marijuana products meet the growing, processing, testing and THC/CBD content specifications in the proposed rules. A retailer with a medical marijuana endorsement who carries products that comply with the proposed rules may be more likely to increase its sales to medical marijuana patients. A producer or processor that complies with the proposed rules may be more likely to increase its sales of compliant products. A testing lab that complies with the proposed rules may be more likely to increase its services (sales) to processors seeking to sell products that comply with the proposed rules.

Analyze whether the proposed rule may impose more than minor costs on businesses in the industry.

The proposed rules are anticipated to impose more than minor costs to businesses that must comply.

Licensed marijuana producers and processors would incur testing costs based on the type of testing performed, the volume of product tested, and any retesting required. Five certified testing labs were surveyed to determine the estimated average cost per test by type. The results are shown in the table below:

Heavy Metals	Mycotoxin	Pesticides
Range - \$85 to \$350	Range - \$25 to \$350	Range - \$100 to \$350

Certified labs tested approximately 14,433 lots of marijuana from December 1, 2014 to November 30, 2015. Medically endorsed retail stores will eventually be required to have at least twenty-five percent of product inventory tested for compliance. Based on this data the result is approximately 3, 608 lots of marijuana will be subjected to the tests in these rules.

Producer and processor sales for the same time period totaled \$17,719,649.00. Based on an estimated cost of \$210.00 for all three tests, total compliance test costs are estimated to be \$757,732.50 or approximately four percent of producer and processor total sales.

Current certified testing labs that have already purchased equipment and are performing testing of marijuana products would incur costs for maintenance of existing equipment, and the purchase of replacement or upgrades to equipment. New certified testing labs would incur equipment purchase costs based on the type of testing equipment purchased. The annual costs of testing equipment can be calculated as one-tenth of these one-time costs using standard ten year life of machine. Additional costs would be for extra equipment necessary for optional testing. Five certified testing labs were surveyed to determine the average cost of various types of marijuana product testing equipment. The results are shown in the table below:

Heavy Metals	Mycotoxin	Pesticides
Range - \$160,000 to \$350,000	Range - \$12,000 to \$16,000	Range - \$150,000 to \$500,000
Average - \$253,000	Average - \$14,000	Average - \$325,000

Determine whether the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

The proposed rules are not anticipated to have a disproportionate impact on small versus large marijuana producers, processors and certified testing labs. Certified marijuana testing laboratories are small businesses so there are no large businesses to determine any possible impact. The impact on producers and processors is indeterminate at this time, but it is assumed that the costs previously identified will be passed on in final product sales, resulting in a market driven but minimal cost impact.

We worked with stakeholders during the development of these proposed rules to discuss alternative testing standards and their costs. The proposed rules provide appropriate product testing needed to protect public health and safety, while allowing producers and processors the ability to bring their products to market with the minimum risk of disease or damage (e.g. mold, insects).

Describe how small businesses were involved in the development of the proposed rule.

The department conducted four stakeholder meetings, collecting input verbally and in writing on the proposed rule. Stakeholders included marijuana producers, processors, licensed retail store owners, employees, customers and other interested parties.

Identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule.

Producers and processors do not have to grow and create these products nor do retail stores have to carry these products if they do not wish to be medically endorsed. Therefore the department does not anticipate any lost jobs due to the rules.

The rule does create opportunities to expand the market and business of all three license groups as well as certified labs. This could result in increased business and lead to the hiring of additional staff.

Here you can compare compliance costs with revenues for the three groups if you have revenue data available. For example we can compare the additional costs of producers (unit costs) with the sale value of the same amount that producers sell to their clients (those who buy from them).