

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).