

Significant Legislative Rule Analysis
Chapter 246-70 WAC
A Rule Concerning Medical Marijuana Product Compliance
May 13, 2016

SECTION 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

This is a supplemental proposal to proposed rules filed on February 16, 2016 as WSR 16-05-079.

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. These standards include requirements for a product to be classified as a compliant marijuana product.

The proposed rule is one piece of the overall implementation of regulation for medical marijuana and is mandated by enabling legislation passed in 2015(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. In general, the law directs the department to:

- Contract with a third party to create and administer a medical marijuana authorization database
- Adopt rules relating to the operation of the database
- Adopt rules regarding products sold to patients and their designated providers
- Consult with the WSLCB about requirements for a retail store to get a medical marijuana endorsement
- Create a medical marijuana consultant certification program
- Develop and approve continuing education for healthcare practitioners who authorize the medical use of marijuana
- Make recommendations to the legislature about establishing medical marijuana specialty clinics

The purpose of the product compliance standards is to establish requirements for products that may be beneficial for medical use including quality assurance testing (pesticides, mycotoxins, heavy metals), product labeling, and safe handling and employee training standards.

The department has filed three emergency rules to date on marijuana product compliance. The most recent emergency rule was filed May 18, 2016. Emergency rules were necessary to ensure enough time for marijuana producers, processors and testing labs to prepare for the alignment of medical and recreational marijuana on July 1, 2016.

The first proposal for permanent rulemaking was filed in February 2016 with two public hearings held in March of the same year. Based on stakeholder feedback and consultation with partner state agencies, the department is filing a supplemental rule proposal to address additional changes to rule language. The following are changes to the original proposal made in the supplemental:

- Designate the actual logos allowed to be used on products compliant with this chapter (“General Use,” “High THC,” “High CBD”) along with the requirement the logo must be either dark blue or black in color.
- Clarify that products not meeting the definition for “High CBD” compliant products may meet standards for “General Use” compliant products.
- Allow marijuana producers and processors to petition the Washington State Liquor and Cannabis Board (WSLCB) to re-test a failed harvest, batch, or lot according to WSLCB rules.
- Remove the zero tolerance standard for pesticide residue and instead allow for pesticide and heavy metal action levels adopted by the WSLCB in rule.
- Clarify that failed harvests, batches, or lots must be destroyed according to WSLCB rulemaking.

SECTION 2:

Is a Significant Analysis required for this rule?

Yes. The proposed rule adopts a new regulatory program, and violation of the rules may result in a penalty or sanction. As defined in chapter 34.05 RCW, the department has determined that portions of the proposed rules require a significant analysis. The department, however, has determined that no significant analysis is required for the following portions of the rules.

Table: Non-Significant Rule Identification

#	WAC Section	Section Title	Reason
1	WAC-246-70-010	Findings	Does not meet the definition of a legislatively significant rule
2	WAC-246-70-020	Applicability of WSLCB rules	Does not meet the definition of a legislatively significant rule
3	WAC-246-70-030	Definitions	Does not meet the definition of a legislatively significant rule
4	WAC-246-070-090	Marijuana product compliant logos	Does not meet the definition of a legislatively significant rule

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements. The statute's intent is to establish the regulation of production, processing and retail sale of medical marijuana under the authority of the WSLCB. The law intends to ensure safe, consistent, and adequate access to marijuana for qualifying patients. The requirements in this chapter are in addition to all WSLCB requirements in chapter 314-55 WAC. The intent of the rules for medical marijuana product compliance is to build upon all other existing requirements for licensed marijuana producers, processors and retailers, and certified third-party labs. The objectives of the proposed rules include:

- Adding a new section that states the requirements of this chapter are in addition to all the WSLCB requirements in chapter 314-55 WAC.
- Adding a new section to define terms used throughout the chapter.
- Adding a new section that states the requirements for a product to be classified as a compliant marijuana product.
- Adding a new section that states the testing requirements for compliant products.
- Adding a new section that states the labeling requirements for compliant products.
- Adding a new section that states the safe handling requirements for compliant products.
- Adding a new section that states the requirements for employee training on compliant products.
- Adding a new section that states the requirements for use of marijuana compliant logos.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

RCW 69.50.375 and 82.08.9998 direct the department to adopt rules establishing standards for marijuana product compliance. No alternatives to rulemaking are available.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

During the rulemaking process the department collected input from stakeholders interested in the proposed rule. Details on responses are included in the section analysis below.

This proposal created a total of eight sections of rule. There are five legislatively significant sections analyzed below.

1. WAC 246-70-040 Marijuana products compliant with this chapter.

Description of the proposed rule: The proposed rule establishes the requirements for a marijuana product to be classified and labeled as compliant, using the logo identified in proposed WAC 246-70-090 to indicate compliance with this chapter. The rule also establishes the following classifications of compliant marijuana products:

- General use compliant products
- High THC compliant products
- High CBD compliant products

Cost/Benefit Analysis: The proposed rule establishes the compliance requirements for categorizing marijuana products and identifying the products to the purchaser. The rule also establishes the use of the logo in the proposed rules to indicate compliance with this chapter. The benefit of the rule is that it sets compliance standards for marijuana products and identifies quality assured products with a department approved logo. Because potency tests are already required by the WSLCB this section does not add any testing costs for the processors or producers to identify THC and CBD levels. The rule benefits qualifying patients and designated providers by providing access to quality assured products labeled as compliant. There is no cost to download the department logo in proposed WAC 246-70-090, and the processors can choose to incur a one-time minimal cost to add the logo to existing product packaging. In the alternative, the processors may choose to pay a minimal cost to have labels pre-printed in bulk. The cost for pre-printed labels are estimated at \$44.80, which would be enough to label a five pound lot of marijuana packaged in one gram units. The total cost for labeling cannot be determined until processors begin packaging compliant products to be sold in medically endorsed retail stores on July 1, 2016, using the department approved logo.

2. WAC 246-70-050 Quality assurance testing.

Description of the proposed rule: The proposed rule establishes testing requirements 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). Pesticide screening must not exceed the action levels set by the WSLCB in rule. At the producer or processor's request, the WSLCB may authorize a retest to validate a failed test. 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 any imported cannabinoid used in a marijuana product.

Cost/Benefit Analysis: The proposed rules establish the requirements for testing, and the sample sizes and intervals for testing by a third-party testing lab certified by the WSLCB. The cost of testing by a certified third-party lab varies, according to the type of test and number of tests required.

A survey of certified testing labs returned the following average costs per test:

- Heavy metal screening - \$85-\$350
- Mycotoxin screening - \$25-\$350
- Pesticides screening - \$100-\$350

Approximately 43,300 marijuana product tests were performed pursuant to WSLCB rules from December 1, 2014 to November 30, 2015. Fourteen certified labs performed the tests. Equipment costs for certified third-party testing labs vary according to the type of testing performed and the brand of equipment purchased by the lab. A survey of certified testing labs returned the following average equipment costs:

- Heavy metal screening - \$255,000
- Mycotoxin screening - \$12,000
- Pesticides screening - \$325,000
- Fume hood (additional) - \$160,000

There are some 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 life of the equipment, and the need for any additional testing required to meet the standards of WAC 314-55-102. The number of processors requiring product testing will increase based on licensing data from the WSLCB.

The benefit of the rule is that it establishes reasonable additional testing standards for marijuana products, ensuring qualifying patients and designated providers have access to quality assured products.

3. WAC 246-70-060 Compliant product labeling.

Description of the proposed rule: The proposed rule establishes the requirements for compliant marijuana product labeling using the logo developed by the department. The rule

specifically identifies what cannot be used for labeling compliant marijuana products including:

- Any word(s), symbol, or image commonly used in or by medical or pharmaceutical professions
- Any statement or implication of a specific medical or therapeutic benefit
- Any word(s) or image that mimic a brand of over-the-counter or legend drug
- Colors other than black or dark blue when printing the department approved logo.

Cost/Benefit Analysis: The proposed rule establishes the requirements for labeling compliant marijuana products. The cost to the processors is minimal, as there is no cost to download the logo in proposed WAC 246-70-090, and the processors can choose to incur a one-time minimal cost to add the logo to existing product packaging. The processors may elect to pay a minimal cost to have logos pre-printed in bulk, costs for pre-printed logos are estimated at \$44.80 per five pound lot of product. The benefit of the rule is it will ensure patients and designated providers may select compliant quality tested marijuana products identified by the logo.

4. **WAC 246-70-070 Compliant product safe handling.**

Description of the proposed rule: The proposed rule establishes the requirements for all processing facilities that create or handle marijuana-infused products to be constructed, kept and maintained in a clean and sanitary condition. This rule is in accordance with rules prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.

The proposed rule also requires that marijuana processors that do not create or handle marijuana-infused products and all marijuana producers must 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/Benefit Analysis: The proposed rule establishes requirements for all marijuana and marijuana-infused product processing facilities to ensure the facility operations are conducted in accordance with adequate sanitation and safe-handling principles. The cost to the businesses for sanitary equipment, adequate water supply, and adequate toilet facilities for employees would be minimal, not cause a loss of sales or revenue, and may already be in required by other regulatory entities such as the Department of Labor and Industries or the Department of Agriculture. The administrative cost to businesses to create policies and procedures for the use of sanitary equipment and safe-handling practices would be a minimal amount of staff time and again, may already be in place based on requirements from other regulatory entities. The benefit of the rule is that it ensures all marijuana processing facilities comply with sanitation and safe-handling principles to provide safe products.

5. WAC 246-70-080 Employee training.

Description of the proposed rule: The proposed rule requires marijuana producers, processors and retailers to adopt and enforce policies and procedures to ensure employees and volunteers receive training about the requirements of this chapter.

Medically endorsed retail stores additionally require the following training:

- Procedures regarding the recognition of valid authorizations and the use of equipment to enter qualifying patients and designated providers into the medical marijuana database
- Identification of valid recognition cards
- Adherence to confidentiality requirements
- 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.

Cost/Benefit Analysis: The proposed rule establishes the requirements for employee training by marijuana producers, processors and retailers on this chapter. The cost to the employers is minimal, based on the estimated time of 8 hours of administrative time to draft policies and procedures, and 2 hours of on the job training on the procedures per employee. 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, for all basic retail outlet training.

Cost Benefit Summary

The proposed rule creates a consistent process for ensuring qualifying patients have adequate access to marijuana products that are compliant with this chapter. The cost to producers and processors for product testing and labeling are reasonable when compared with the benefits of providing safe products to qualifying patients. The rules establish testing standards for medical products that will exceed the current recreational market standards. The rules also establish minimal requirements for retail stores to train employees so that medical patients are assisted properly and given adequate confidentiality. Therefore the total probable benefits of the rule exceed the total probable costs.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

One alternative to these rules would be to make rules limiting medical patients to certain marijuana products such as only high CBD/low THC products or products that cannot be smoked. 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 for medical use is best made by patients in consultation with their health care practitioners. For this reason, the department decided not to limit the types of products available to qualifying patients. Instead, the department is proposing standards for products that any consumer can rely upon to be reasonably safe and meet quality assurance measures.

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The proposed rule does not require those to whom it applies to take an action that violates requirements of another state law.

The proposed rule also does not require any person to violate federal law. However, those persons who voluntarily choose to be involved in the production, processing or sale of marijuana are technically violating federal law because marijuana remains a schedule 1 controlled substance under federal law. On August 29, 2013, Deputy U.S. Attorney James M. Cole issued a memorandum entitled “Guidance Regarding Marijuana Enforcement.” In the memo, Deputy Attorney General Cole listed eight priorities related to marijuana. He stated the federal government’s expectation that states that “have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests.” Jurisdictions that “implement strong and effective regulatory and enforcement systems” are less likely to threaten the federal priorities. States whose regulation is not as robust may be challenged by the federal government and individuals may be prosecuted.

These rules contribute to a strong and effective regulatory system in Washington by ensuring patients have adequate, safe and consistent access to marijuana products and are not forced to purchase marijuana from the black market.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The proposed rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule differs from federal law because federal law prohibits the possession and sale of marijuana. However, the rule conforms to the Cole memo because it contributes to a strong and effective regulatory system and is consistent with the federal government's eight priorities.

While marijuana remains an illegal substance under federal laws, the current administration provided guidance regarding marijuana enforcement that allows states to pursue legalization. The guidance does require states that do legalize marijuana to "implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests." The department works carefully with other state agencies to ensure our work to enact 2SSB 5052 and 2E2SHB 2136 follows this guidance.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The proposed rule is coordinated to the maximum extent practicable with other applicable laws, including current medical cannabis law under chapter 69.51A RCW.

The rule has been coordinated with other state rules to ensure a consistent and comprehensive regulatory system in Washington. While it inherently conflicts with federal law, it conforms to the Cole memo.