



# Standards for Marijuana Products Intended for Medical Use

Rules Public Hearings  
March 22 & 25, 2016

# Rulemaking Process

WA Medical Marijuana Program

# Rulemaking Process

- When the legislature passes a law, they may direct an agency to create rules to implement the law.
- When conducting rulemaking, the department must follow the requirements in:

**Administrative Procedure Act, chapter 34.05 RCW**  
and

**Regulatory Fairness Act, chapter 19.85 RCW**

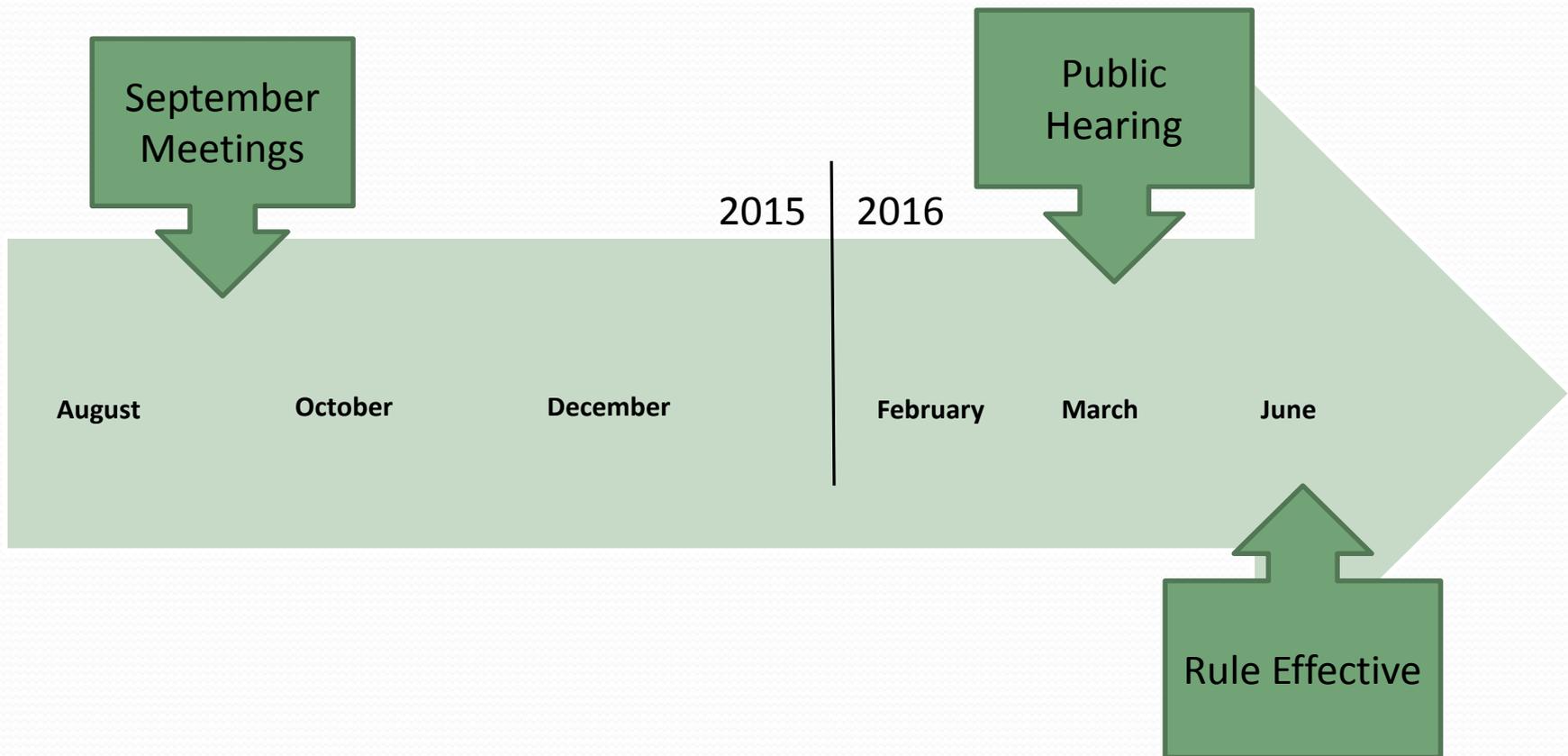
- Stakeholders interested in the department's rulemaking activities should join our ListServ.

# SB 5052

## DOH Required Rules

- Establish a Patient Authorization Database
- Establish a Consultant Certification
- Establish Product Requirements

# Product Rule Proposed Timeline



# History of Legislation

**Cannabis Patient Protection Act**

# History of Legislation

- 1998: I-692 Permitted patients with certain conditions to use medical marijuana.
- 2008: 60-day supply for patients was defined as 24 ounces and 15 plants.
- 2012: I-502 Licenses and regulates marijuana production, distribution, and possession for persons 21 and over.
- On April 24, 2015, Gov. Inslee signed 2SSB 5052, the **Cannabis Patient Protection Act**. It directs the Department of Health to complete the following:

# SSB 5052

## DOH Requirements

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

# DOH Goals for SSB 5052

- Protect access for patients with qualifying conditions.
- Ensure safe, quality tested and accurately labeled products for patients.

# Product Compliance Rules

**RCW 69.50.375, Marijuana Retailers – Medical Endorsement**

**RCW 82.08.998, Retail Sales Tax**

# Product Rules for RCW 69.50.375

For products that may be sold or donated to patients at a medically endorsed retail store, DOH must determine:

- THC and CBD concentrations/ratios
- Labeling requirements
- Testing for pesticides, mold, fungus, solvents, etc.
- Safe handling requirements
- Employee training requirements

# How the Rules Address RCW 69.50.375 Requirements

## **The Rules Do:**

- Create voluntary standards for safer and healthier products.
- Allow consumers the choice of compliant or regular products.

## **The Rules Do Not:**

- Differentiate between “medical and “non-medical” marijuana.
- Limit the types of products a patient with a recognition card will be able to purchase.

# Product Rules for RCW 82.08.998

- DOH must identify products that may be beneficial for medical use.
- Identified products will be sold without sales tax.

# How the Rules Address RCW 82.09.998 Requirements

## **The Rules Do:**

- State that the determination of what is medically beneficial should be made between the patient and his/her healthcare practitioner.
- Create ratios for high CBD/low THC products that are sales tax free for any adult.

## **The Rules Do Not:**

- Limit concentrates or extracts to only these ratios.
- Limit patients to only products containing these ratios.

# Marijuana Product Purchases

	High THC Compliant	High CBD Compliant	General Use Compliant	Any Product Available for Sale in a Retail Store with a Medical Endorsement
Patients and Designated Providers with Recognition Card*	✓	✓	✓	✓
Any Adult Consumer		✓	✓	✓

\*All purchases made by a card holder are sales tax free at 3 times the recreational purchase limits.

Cards can be obtained in medically endorsed stores on July 1, 2016.

# Emergency Rules Filed

- Filed emergency rules on October 5, 2015:
  - Producers, processors and labs needed time to prepare before July 1, 2016.
  - New retailers and existing retailers seeking a medical endorsement needed to know what the requirements will be.
- Also filed documents to begin permanent rulemaking on October 5.
- Emergency rules re-filed in early February with minor changes.

# WAC 246-70

A review of the rules being proposed.

# WAC 246-70

- **010 – Findings**

- The use of marijuana may be beneficial to alleviate the symptoms of certain physical and mental conditions.
- Federal classification of marijuana as a schedule 1 controlled substance means scientific research has not been performed that would allow for standardized indications of particular strains.
- The decision of what marijuana products may be beneficial is best made by patients in consultation with their health care practitioners.
- Types of products available to qualifying patients is not limited; creates standards for products that meet quality assurance measures.

# 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.

- **030 – Definitions**

- Allowed pesticides
- Batch
- Certified third-party testing lab
- Harvest
- Imported cannabinoids

# WAC 246-70

- **040 – Marijuana products compliant with this chapter**
  - **General Use**

Any marijuana product approved by WSLCB and meeting the requirements of this chapter, including edibles.
  - **High THC**

A marijuana product meeting the requirements of this chapter containing more than ten but no more than fifty milligrams of THC per serving or application (capsules, tinctures, transdermal patches, suppositories).

# WAC 246-70

## ■ High CBD

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:

- Marijuana extracts containing not more than 2% THC concentration and at least 25 times more CBD concentration by weight.
- Marijuana-infused edible products containing not more than 2 milligrams of active THC and at least 5 times more CBD per serving by weight for solids or volume for liquids.
- Marijuana-infused topical products containing at least 5 times more CBD concentration than THC concentration.

# WAC 246-70

- **050 – Quality assurance testing**
  - Third-party testing lab
    - Pesticide screening and heavy metal screening
    - Mycotoxin screening when ever microbial testing is required
    - Allows for **imported cannabinoids**, and requires additional pesticide and heavy metal screening
  - Pesticide screening
    - Allowed pesticides
    - Also screen for pyrethrins and piperonyl butoxide
  - Allows for **specific terpenes** to be added to a marijuana product other than useable marijuana.
    - Terpenes naturally occurring in marijuana; or
    - Terpenes permitted or generally recognized as safe by, and used in accordance with, 21 C.F.R., Chapter I, subchapter B.

# WAC 246-70

- **060 – Compliant Labeling**

- Products must be readily identifiable by placement on the product's label.
- A logo may not be used on any object or merchandise other than a compliant marijuana product.
- Labels for compliant products must not use any medical or prescription symbols or imply medical or therapeutic benefit.
- The label must prominently display the following statement: "This product is not approved by the FDA to treat, cure, or prevent any disease."
- Marijuana products that use a logo but do not meet the requirements in this chapter will be reported to the WSLCB.

# WAC 246-70

- **070 – Compliant product safe handling**
  - Processing facilities are clean and sanitary
  - Adequate lighting
  - Identify any toxic cleaning products
  - Sufficient water supply

# WAC 246-70

- **080 – Employee training**

- Producers, processors and retailers adopt and enforce policies and procedures to ensure all employees receive training.
- Retailers holding medical marijuana endorsement will train employees to:
  - Identify valid authorizations and recognition cards and use the database for validation
  - Adhere to confidentiality
  - Use science-based information about products when assisting qualifying patients
- No employee is to act like a medical provider.

# WAC 246-70

- 090 – Marijuana product compliant logos



# Wrap Up, Next Steps

- **What happens next?**
- **Where can we find a summary of comments received?**

*Thank you*

# Contact Information

## Website

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