

Medically Compliant Cannabis Packaging Approval Guidance

Title: Number:	Substitute House Bill (SHB) 1453 Cannabis Excise Tax Exemption GD24-02
Laws:	RCW 69.50.101; RCW 69.50.360; RCW 69.50.363; RCW 69.50.535
Rules:	WAC 314-55-077, WAC 314-55-105, WAC 314-55-106
	WAC 246-70-040; WAC 246-70-050; WAC 246-70-060; WAC 246-70-
<u>090</u>	
Resources:	House Bill (SHB) 1453; GD24-01; WAC 314-55-083; WAC 314-55-087;
	<u>WAC 314-55-089;</u>
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Guidance Date: July 12, 2024	
Requested	By: Cannabis Stakeholders

<u>Purpose</u>: This document provides guidance on medically compliant cannabis packaging and labeling, including approvals for medically compliant cannabis-infused edible packaging.

Summary:

Cannabis retailers **may not** update existing packaging to reflect any status change of a cannabis product which has been retested to medically compliant product standards.

A licensed cannabis processor may add the appropriate logo to a previously approved cannabis-infused product package without obtaining further packaging approval from the Liquor and Cannabis Board (LCB) if it has existing approved packaging that already contains:

- 1) The mandatory FDA statement and warning symbol, and
- 2) Serving sizes in accordance with Department of Health (DOH) compliant product standards.

Any prior label approvals for cannabis-infused edibles that do not contain both 1) and 2) above must obtain LCB approval for a new label before adding the DOH compliant product logo.

Background: Substitute House Bill 1453, chapter 79, Laws of 2024 provides a temporary exemption from the 37% excise tax levied in RCW 69.50.535 for sales that satisfy three conditions:

1) The purchaser is a patient registered in the Department of Health's Authorization database with a valid recognition card,

- 2) The product purchased is cannabis identified by the Department of Health as compliant with <u>WAC 246-70-040</u>,
- 3) The medically compliant product purchased is from a retailer with a medical cannabis endorsement.

This exemption is scheduled to expire June 30, 2029.

Current cannabis licensees have expressed an interest in retesting cannabis product to meet DOH rule standards for medically compliant product. Additionally, cannabis licensee expressed an interest in an allowance to place a DOH medically compliant sticker with the appropriate logo pursuant to <u>WAC 246-70-090</u> to existing product in retail stores, and without needing to have cannabis-infused edible packaging and labeling reapproved by the LCB. The purpose of the request is to provide an expedited way of allowing retailers to provide the 37% excise tax exemption to medical cannabis patients purchasing medically compliant product.

Analysis and Considerations:

Several regulations are in place to ensure any cannabis product identified as DOH medically compliant cannabis meets standards associated with product testing, warning statements, serving size, and approved logos. To ensure compliance, packaging and labeling is reviewed and approved by the LCB for edible products. Associated laws and rules include:

- WAC 246-70-040 Compliant product
- WAC 246-70-050 Heavy metal testing
- <u>WAC 246-70-060</u> Mandatory statement on label
- <u>WAC 246-70-090</u> Logos for medically compliant product
- <u>WAC 314-55-077</u> Cannabis processor license privileges and label approvals
- WAC 314-55-079 Cannabis retailer license privileges
- WAC 314-55-105 Statements on packaging
- <u>WAC 314-55-106</u> Cannabis warning symbol requirements
- <u>RCW 69.50-101</u> Definitions of a licensed processor and retailer
- <u>RCW 69.50.360</u> Cannabis retailer license privileges
- <u>RCW 69.50.363</u> Cannabis processor license privileges

Packaging and labeling requirements for medically compliant product differ from non-medically compliant product. The addition of a DOH logo sticker alone may cause non-compliance with some of the regulations. For example, if a logo sticker were to be placed over the universal warning symbol, approved packaging would no longer be compliant. Further, if the FDA warning statement, "this product is not approved by the FDA to treat, cure, or prevent any disease," for medically compliant cannabis was not present on the previously approved non-medically compliant packaging, then the addition of a sticker alone would not ensure compliance with existing regulation <u>WAC 246-70-060(3)</u>.

Serving size restrictions for cannabis-infused edible products also differ between medically compliant cannabis and non-medically compliant cannabis. For example, non-medically compliant cannabis-infused edible products available to all customers over 21 years of age may have up to 10mg of THC per serving or 100mg THC per package. There are no limitations related to the numbers of servings in a package, so a package could contain 20 servings containing 5mg THC per serving, and still be compliant with the 100mg THC per package

limitation. Conversely, medically compliant products have different standards. For example, "general use" compliant cannabis-infused edible product may have up to 10mg of THC per serving, and 100mg THC per package, but is limited to only 10 servings total per package (WAC <u>246-70-040(1)(b)</u>). If a logo sticker were added to a non-medically compliant product, the difference in product and labeling requirements would not automatically ensure continued packaging compliance.

Pursuant to state statute in chapter 69.50 RCW, licensed processors have the privilege and responsibility of packaging and labeling cannabis products for retail sale. Retailers only have license privileges to sell cannabis products purchased from a processor that have been properly packaged and labeled. As these license privileges are specific in state statute, modification to packaging and labeling must be conducted by the licensed processor, as labeling is not in the scope of retailer privileges.

Retailers are liable for taxes if the 37% excise tax is applied inappropriately. Licensed retailers rely on approved packaging, certificates of analysis (COA), and the state record keeping system CCRS. For retailers to have confidence in their ability to legally provide the 37% excise tax exemptions to qualifying patients on qualifying products, processors must ensure all packaging, labeling, and records are accurate for products processors sell to retailers. This includes obtaining product, packaging, and labeling approvals for cannabis-infused edibles. The request of having retailers simply add a Department of Health compliant logo sticker to an existing package will not meet this need and would only increase the risk of inappropriate tax exemptions and statutory non-compliance.

DOH and the LCB currently have different sample size regulations for product testing at labs. To meet DOH standards for medically compliant product, all testing samples must be compliant with <u>WAC 246-70-050</u>.

Guidance:

Licensed cannabis processors need to ensure all product being identified as medically compliant cannabis pursuant to Department of Health <u>WAC 246-70-040</u>, must be compliant with all packaging and labeling standards in WAC 246-70 and WAC 314-55. To be compliant and eligible for the medical excise tax exemption, each medically compliant product package must contain the following:

- The statement: "This product is not approved by the FDA to treat, cure, or prevent any disease." (WAC 246-70-060)
- Appropriate logo found in <u>WAC 246-70-090</u>
- Universal symbol for all products (WAC 314-55-106(2))
- "Not for kids" warning symbol for cannabis-infused products for oral ingestion (<u>WAC</u> <u>314-55-106(1)</u>)



- "General use compliant product"
 - For products meeting the requirements of WAC 246-70, including approved cannabis-infused edible products, and cannabis products with CBD/THC ratios that do not qualify as "high CBD compliant products."

 General use cannabis-infused edible products may be packaged in servings or applications containing up to ten milligrams of active THC and a package must not contain more than ten servings or applications and must not exceed one hundred total milligrams of active THC.



- "High THC compliant product"
 - For cannabis products containing more than ten but no more than fifty milligrams of THC per serving or application and meeting the requirements of WAC 246-70
 - Packages must not contain more than ten servings or applications and must not exceed five hundred total milligrams of active THC.
 - Only the following products may qualify as a high THC compliant product (WAC 246-70-040(2))
 - Capsules and tablets
 - Tinctures
 - o Transdermal patches
 - Suppositories



- "High CBD compliant product"
 - For extracts containing not more than two percent THC concentration and at least twenty-five times more CBD concentration by weight.
 - For 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.
 - For infused topical products containing at least five times more CBD concentration than THC concentration.

If a licensed processor has existing approved cannabis-infused edible product packaging that already contains the mandatory FDA statement and warning symbol, and the approved package currently contains serving sizes in accordance with DOH compliant product standards, then the processor may add the appropriate logo to the approved cannabis-infused edible package without needing further packaging approval from the LCB. Other products that are not cannabis-infused edibles, would also need to contain the mandatory FDA statement to be compliant if an appropriate logo sticker is added to the package.

If a licensed processor has approved packaging that **does not** contain the mandatory FDA statement or does not meet product serving sizes in accordance with DOH compliant product standards, then the previously approved packaging would not be eligible for sale to a retailer, and packaging for a cannabis-infused edible would need to be submitted to the LCB for approval to include the DOH logo.

Cannabis retailers **may not** update existing packaging to reflect any status change of a cannabis product which has been retested to medically compliant product standards.

Cannabis retailers are encouraged to double check Certificates of Analysis (COA) for any incoming medically compliant product they have purchased to ensure heavy metal testing has been conducted.