



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Washington State Liquor and Cannabis Board

- Preproposal Statement of Inquiry was filed as WSR 16-07-156 ; 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)
WAC 314-55-225 Marijuana recalls.

Hearing location(s):

Washington State Liquor and Cannabis Board
Board Room
3000 Pacific Ave SE
Olympia, WA 98504

Date: July 13, 2016 Time: 10:00 am

Submit written comments to:

Name: Joanna Eide, Policy and Rules Coordinator
Address: PO Box 43080
Olympia, WA 98504
e-mail rules@lcb.wa.gov
fax (360)664-9689 by (date) July 13, 2016

Assistance for persons with disabilities: Contact

Joanna Eide by July 6, 2016

TTY () _____ or (360) 664-1622

Date of intended adoption: on or after July 27, 2016
(Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of this proposal is to establish a process and requirement for recalls of marijuana and marijuana products, and to provide guidance for marijuana businesses that wish to conduct market withdrawals. This proposal creates a new section in chapter 314-55 WAC. Marijuana licensees will have to comply with the new recall requirements and create a recall plan should they be subject to a recall event. Notification requirements are included, as well as reporting requirements should a recall be required.

Reasons supporting proposal: Marijuana and marijuana products sold in WSLCB licensed retail stores are a consumable product and it is important that they are safe for human consumption. In the event that product posing a risk to consumers is discovered, rules are needed to establish the process and requirements for marijuana recalls to allow for affected product to be identified and removed from the marketplace in a fast and efficient manner. The recall process established in this proposed rule is based on similar processes and requirements in other industries that produce consumable products, and is modeled after the Washington State Department of Agriculture's recall procedures.

Statutory authority for adoption: RCW 69.50.342 and 69.50.345

Statute being implemented: RCW 69.50.342 and 69.50.345

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: **May 18, 2016**

TIME: **11:17 AM**

WSR 16-11-113

DATE
May 18, 2016

NAME (type or print)
Jane Rushford

SIGNATURE

TITLE
Chair

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None.

Name of proponent: (person or organization) Washington State Liquor and Cannabis Board

- Private
 Public
 Governmental

Name of agency personnel responsible for:

| Name | Office Location | Phone |
|---|--|----------------|
| Drafting..... Joanna Eide, Policy and Rules Coord | 3000 Pacific Ave SE, Olympia, WA 98504 | (360) 664-1622 |
| Implementation.... Tim Gates, Marijuana Examiners | 3000 Pacific Ave SE, Olympia, WA 98504 | (360) 664-1622 |
| Enforcement..... Justin Nordhorn, Chief Enforcement | 3000 Pacific Ave SE, Olympia, WA 98504 | (360) 664-1726 |

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 or school district fiscal impact statement.

A copy of the statement may be obtained by contacting:

Name: Joanna Eide, Policy and Rules Coordinator

Address:

3000 Pacific Ave SE

Olympia, WA 98504

phone (360) 664-1622 _____

fax (360)664-9689 _____

e-mail Joanna.Eide@lcb.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:

Address:

phone () _____

fax () _____

e-mail _____

No: Please explain: A cost-benefit analysis was not required under RCW 34.05.328.



Date: May 18, 2015

To: Jane Rushford, Board Chair
Ruthann Kurose, Board Member

From: Joanna Eide, Policy and Rules Coordinator

Copy: Rick Garza, Agency Director
Justin Nordhorn, Chief of Enforcement
Becky Smith, Licensing Director
Tim Gates, Interim Marijuana Examiners Unit Supervisor

**Subject: Small Business Economic Impact Statement
Marijuana Product Recall Rules**

A small business economic impact statement has been prepared under chapter 19.85 RCW.

Small Business Economic Impact Statement:

WAC 314-55-225 Marijuana recalls.

1. Description of reporting, record keeping and other compliance requirements of the proposed rule:

WAC 314-55-255, Marijuana recalls, is a proposed new WAC section that details a new process for recalls of marijuana. It contains new several reporting and other compliance requirements, some which apply to all licensees and some that will only apply to licensees that conduct a “market withdrawal” or are affected by a recall event.

- a) The following requirement applies to all licensees: Creation of a recall plan within 60 days of the effective date of the proposed rule. The recall plan details the procedures a licensee will follow should the licensee be affected by a recall event.
- b) The following new requirements will only apply to licensees who conduct a market withdrawal or are affected by a recall (case-by-case basis):
 - a. Reporting to a local WSLCB enforcement officer when conducting a “market withdrawal;”
 - b. Immediately notifying a local WSLCB enforcement officer when initiating a recall;



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- c. Tracking of affected product and the amount of affected product returned to the licensee as part of the recall effort; and
- d. Recall status reporting throughout a recall event at a minimum of once per week during a recall;

The recall requirements in the proposed rule are similar to recall requirements in other industries that produce consumable products and mirror the recall requirements of the Washington State Department of Agriculture (WSDA).

2. Kinds of professional services that a small business is likely to need in order to comply with such requirements:

There are no professional services licensees will need to create a recall plan or to comply with the requirements of a recall event. The WSLCB will make a recall plan example available for licensees to use in creating a licensee's individual recall plan. A licensee may elect to retain professional services, but should not require them in order to comply with the provisions of the proposed rule.

3. Costs of compliance for businesses, including costs of equipment, supplies, labor and increased administrative costs:

The only cost for compliance that will impact all licensees are employee hours in creating a recall plan. These costs will be mitigated by the WSLCB making a recall plan example available for licensees to use in creating a licensee's individual recall plan. Additionally, because each licensee compensates its employees at different rates, and the WSLCB does not collect or have access to data on the amounts employees are paid, these costs will vary by licensee. WSLCB estimates that costs associated with complying with the new requirements in the proposed rules related to creating a recall plan should be minimal as it should take no more than 10-20 hours of work to complete.

Whether a licensee will incur costs due to involvement in a recall is indeterminable as recalls will only be initiated on a case-by-case basis. It is not possible to determine whether a licensee will be subject to a recall in advance of the discovery of a condition warranting a recall.

4. Will compliance with the rules cause businesses to lose sales or revenue?

A recall event may cause licensees to lose sales or revenue. It is important to note that a recall event will most often be triggered by a licensee failing to follow WSLCB rules for the production of marijuana. The amount of sales or revenue that may be lost is indeterminable as it is dependent on several issues.

- a) Whether a recall event is required is dependent on whether conditions exist that require one and can only be determined on a case-by-case basis.



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- b) The amount of product that may be involved in a recall will vary depending on the circumstances and how much product is found to be affected by the condition that gives rise to a recall requirement.
- c) The reaction of consumers to a recall which is difficult to predict and may depend on the licensee's actions during a recall event (i.e. the swiftness at which a licensee responds to a recall and communications to consumers).

If a recall is triggered and product is destroyed, licensees would lose revenue on the product destroyed. This amount would be dependent on how much product is involved in a recall – the amount could be minimal or substantial depending on the circumstances. The average price per gram as of April 30, 2016, was \$8.73/gram at retail and \$3.14/gram at wholesale.

5. Costs of compliance for small businesses compared with the cost of compliance for the ten percent of businesses that are the largest businesses required to comply with the proposed rules using one or more of the following as a basis for comparing costs:

- a. **Cost per employee;**
- b. **Cost per hour of labor; or**
- c. **Cost per one hundred dollars of sales**

Virtually all marijuana businesses are small businesses. However, these businesses vary in size, costs per employee, costs per hour of labor, and costs per one hundred dollars in sales for a multitude of reasons, including license type. Employee compensation and costs per hour of labor data is not collected by or available to the WSLCB, though the WSLCB does collect data on collection on the value of marijuana at retail and wholesale. Depending on whether the licensee is a producer or processor or a retailer, the sales numbers are different due to the variance between wholesale and retail sales. The average price per gram as of April 30, 2016, was \$8.73/gram at retail and \$3.14/gram at wholesale.

The additional costs associated with complying with the new requirements in the proposed rules related to creating a recall plan should be minimal compared to sales revenue as it should take no more than 10-20 hours of work to complete. The costs associated with creating a recall plan are further mitigated by the WSLCB making a recall plan example available for licensees to use in creating a licensee's individual recall plan.

The costs of complying with a recall as provided in the proposed rule is indeterminate as recalls of products cannot be predicted as they are wholly dependent on whether a licensee does not follow board rules or whether a condition is present that would trigger a recall, and the amount of product that will be impacted by a recall will vary depending on the circumstances.



6. Steps taken by the agency to reduce the costs of the rule on small businesses, or reasonable justification for not doing so:

The WSLCB sought to reduce costs on licensees through making a recall plan example available for licensees to use in creating a licensee's individual recall plan. The recall requirements in the proposed rule are similar to recall requirements in other industries that produce consumable products, mirror the recall requirements of the WSDA, and are necessary for consumer protection from products that pose risks to the consumer.

7. A description of how the agency will involve small businesses in the development of the rule:

Most marijuana businesses are small businesses. They are invited to provide feedback to the rules during the rulemaking process.

8. A list of industries that will be required to comply with the rule:

All licensed marijuana licensees will be required to comply with these rules.

9. An estimate of the number of jobs that will be created or lost as a result of compliance with the proposed rule:

Indeterminate. Because recalls of products cannot be predicted as they are wholly dependent on whether a licensee does not follow board rules or whether a condition is present that would trigger a recall, and the amount of product that will be impacted by a recall will vary depending on the circumstances, WSLCB cannot predict whether a recall event will cause a loss of employees for a licensee.

NEW SECTION

WAC 314-55-225 Marijuana recalls. (1) **Definitions.** For the purposes of this section, the following definitions apply:

(a) "Affected product" means marijuana, usable marijuana, marijuana concentrates, or marijuana-infused products subject to a recall.

(b) "Affected licensee" means a licensee whose marijuana, usable marijuana, marijuana concentrates, or marijuana-infused products are subject to a recall. More than one licensee may be an affected licensee in a recall.

(2) **Exempt market withdrawals.**

(a) A licensee may withdraw from the market marijuana, usable marijuana, marijuana concentrates, or marijuana-infused products by its own determination for reasons that do not pose a risk to consumers such as for aesthetic reasons or other similar deficiencies in product or packaging.

(b) If a licensee initiates a market withdrawal for a reason that does not pose a risk to consumers, the licensee must notify the WSLCB by contacting the local WSLCB enforcement officer assigned to the local area within forty-eight hours of beginning the market withdrawal. Licensees withdrawing marijuana, usable marijuana, marijuana concentrates, or marijuana-infused products under this subsection (2), for reasons other than risk to consumers, are exempt from the remaining requirements of this section.

(3)(a) **When a recall is required.** A recall is required when circumstances exist that pose a risk to consumers. Factors that contribute to a determination of a recall situation include, but are not limited to, the following:

(i) Evidence that pesticides not approved by the board are present on or in marijuana, usable marijuana, marijuana concentrates, or marijuana-infused products above the action levels prescribed by board rule;

(ii) Evidence that residual solvents are present on or in marijuana, usable marijuana, marijuana concentrates, or marijuana-infused products at levels above the action levels prescribed by board rule; or

(iii) Evidence of another condition that poses a risk to consumers including, but not limited to, ingredients in marijuana-infused products that are unfit for human consumption.

(b) **Licensee-initiated recalls.**

(i) If a licensee initiates a recall due to a condition that poses a risk to consumers and would make a recall appropriate under this subsection (3), the licensee must:

(A) Immediately notify the local WSLCB enforcement officer; and

(B) Secure, isolate, and prevent the distribution of all marijuana, usable marijuana, marijuana concentrates, or marijuana-infused products that may have been exposed to the condition warranting the recall. The licensee is prohibited from destroying any affected product prior to notifying the WSLCB and coordinating with the local WSLCB officer on destruction activities.

(ii) If the WSLCB determines the licensee fails to engage in recall efforts that meet the urgency of the risk to consumers, the WSLCB may seek a board-directed recall as provided in this section depending on the circumstances.

(c) **WSLCB investigation-initiated recalls.**

(i) If the WSLCB determines that a recall is not appropriate after an investigation, the WSLCB enforcement division may release administrative holds placed on marijuana, usable marijuana, marijuana concentrates, or marijuana-infused products as part of the investigation as appropriate, unless an administrative hold is necessary under a continuing investigation.

(ii) If the WSLCB determines that a recall is appropriate after an investigation, the WSLCB notifies the board and requests the board issue a recall. If the board issues a recall, the WSLCB notifies the affected licensee that is the source of the issue giving rise to a recall.

(d) **Recall plans.** All licensees must develop a recall plan within sixty days of the effective date of this section that sets the procedures the licensee will follow in the event of a recall of the licensee's product or products under the licensee's control. If a licensee becomes an affected licensee as part of a recall and the affected licensee distributed affected product to consumers or to retailers, the affected licensee must immediately notify all licensees that received affected product, and issue a press release and other appropriate public notification to inform consumers of the recall and identifying information about the affected product recalled.

(i) A recall plan must include, at a minimum, the following:

(A) Designation of a member of the licensee's staff who serves as the licensee's recall coordinator;

(B) Procedures for identifying and isolating product to prevent or minimize its distribution to consumers;

(C) Procedures to retrieve and destroy product; and

(D) A communications plan to notify those affected by the recall, including:

(I) How the affected licensee will notify other licensees in possession of product subject to the recall; and

(II) The use of press releases and other appropriate notifications to ensure consumers are notified of the recall and affected product information if the affected product was distributed to consumers.

(ii) A recall must follow the procedures outlined in the recall plan unless otherwise agreed by the WSLCB and the licensee. The affected licensee must ensure recall procedures are conducted to maximize recall of affected product and minimize risks to consumers.

(e) **Destruction of affected product.** An affected licensee must coordinate destruction of affected product with the local WSLCB enforcement officer and allow WSLCB enforcement to oversee the destruction of affected product recalled to ensure the destruction of affected product that poses risks to consumers.

(f) **Recall reports and audit.** The affected licensee must track the total amount of affected product and the amount of affected product returned to the affected licensee as part of the recall effort. The affected licensee must report to the WSLCB periodically on the progress of the recall efforts. The periodic reports must occur at a minimum of once a week or as otherwise specified and agreed to by the WSLCB and the affected licensee in the recall plan.

(g) **Recall closure.** If the WSLCB determines that the recall efforts are successful and risks to public health and safety are no longer present, the WSLCB may recommend closure of the recall to the board.

(4) **Board-directed recall.**

(a) Upon the recommendation by the WSLCB enforcement division, the board may issue a directed recall if:

(i) The affected licensee does not comply with a recall under subsection (3) of this section;

(ii) The affected licensee does not comply with the recall plan or recall reporting requirements under subsection (3) of this section; or

(iii) The WSLCB enforcement division determines that affected product may be diverted or is being diverted from the licensed business, or another circumstance that makes the affected licensee's destruction of the product inadvisable or a risk to consumers.

(b) If the board issues a directed recall, the WSLCB will notify consumers of the recall and all licensees that may possess product affected by the recall if notice has not yet occurred.

(c) Under a directed recall, the WSLCB enforcement division may seek an order for destruction of the affected product from the board.

(i) If the board issues an order for destruction, the WSLCB enforcement division may seize and conduct the destruction of affected product.

(ii) An order for destruction will include notice to the licensee and opportunity for hearing before destruction, unless there is evidence of an immediate danger to public health, safety, or welfare to justify an immediate order for destruction, with an opportunity for an expedited hearing after the destruction.

(d) If a destruction order is issued and the WSLCB seizes product affected by the recall and conducts the destruction of the product, the affected licensee may be responsible for reimbursing the WSLCB for costs associated with product destruction.

(e) If the board finds that an immediate danger to the public health, safety, or welfare requires immediate WSLCB action, a licensee may also be subject to summary suspension under RCW 66.08.150(4).

(5) The WSLCB will maintain a recall web page on its web site of all current and closed recalls of record.