Marijuana Item Recall Plans - Licensees



Marijuana licensees must develop a recall plan that establishes the procedures the affected licensee will follow in the event of a recall of its marijuana product(s).

Per <u>ARM 42.39.312 (2)</u>, a recall of marijuana and/or marijuana products is required when these items pose a risk to public health and safety. Licensees must develop a recall plan that establishes the procedures that alicensee will follow in the event of a recall of its product(s).

The Cannabis Control Division (CCD) has created this document as a guide to assist licensees. This document will establish what a marijuana recall plan is, why a marijuana item recall plan is needed, and what a licensee's recall plan must consist of to be deemed as acceptable by CCD.

What is a licensee marijuana recall plan?

• A marijuana recall plan establishes the procedures that the <u>affected</u> <u>licensee</u> will follow in the event of a recall of its marijuana product(s).

Why would a marijuana item recall be issued and anncounced?

- A recall is based upon evidence that the marijuana product(s) is contaminated or otherwise unfit for human use, consumption, or application due to unacceptable levels of contaminants.*
- A specifically required test was skipped during the testing process.
- The wrong type of test was conducted on the marijuana product, and the required, specific test is still needed.

*determined by the state laboratory at the Department of Health and Human Services (DPHHS)

Who issues a marijuana item recall?

- The affected licensee may voluntarily recall their marijuana product(s) after determining a recall is advised.
- Additionally, CCD or the Department of Health and Human Services (DPHHS) can determine that a marijuana item recall is required.

Who can be potentially impacted by a marijuana item recall?

- Consumers(adult-use)and registered cardholders (medical patients) could be affected.
- The marijuana item recall could affect 1 licensee, or it could affect multiple marijuana licensees.

To be a compliant with a marijuana recall plan per CCD, what must the licensee include in their written recall plan?

- Per <u>ARM 42.39.312 (3)</u>, at a minimum, a recall plan must include the following:
 - An employee of the licensee must be designated to serve as the **recall coordinator.**
 - The licensee must establish procedures to identify and isolate the product(s) to minimize distribution to consumers.
 - Establish procedures to retrieve and destroy product.
 - Establish a communications plan to notify those affected by the recall, including:
 - How the affected licensee will notify registered cardholders and other licensees in possession of affected product.
 - The use of a press release and other appropriate notifications to ensure customers are notified of the recall and affected product information.

What are the duties of the recall coordinator?

• A **recall coordinator** is an employee that is typically tasked with documenting all decisions and actionsrelated to a product recall, managing and coordinating the implementation of the recall, and ensuring that management is kept informed during all stages of the product recall.

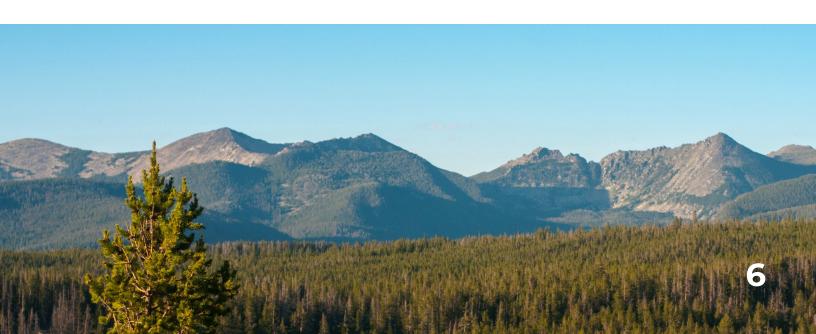
As a licensee's designated recall coordinator, what is an effective means of identifying and isolating the product(s) to minimize distribution to consumers?

- Create a distribution list that includes the name(s), license number(s), and address(es) & phone number(s) of a licensee(s) that has received the affected marijuana product, as well as the date of shipment/transfer of the affected marijuana product.
- List the type of marijuana product(s) being recalled.
- List the harvest batch or production date number of the marijuana product being recalled.



When should a licensee contact CCD concerning marijuana product(s) that may need to be recalled?

- If an affected licensee determines that a marijuana item recall is required, it must **immediately** notify CCD.
- Additionally, the affected licensee must:
 - **Immediately** notify registered cardholders and other licensees that received the affected product.
 - **Immediately** issue a press release or other appropriate public notification to inform customers of the recall and identifying information about the affected product recalled.
 - Provide CCD with a copy of the press release or other appropriate public notification.
 - Post on its own website (licensee), if applicable, information about the recall and the affected product.
 - Perform a causation analysis to determine the issue or issues leading to the recall and provide CCD with a <u>corrective action</u> report and preventative action report, as both are defined by the Department of Public Health and Human Services, which details how the affected licensee plans to correct and prevent future recalls.



What if CCD or the Department of Health and Human Services (DPHHS) determines that is marijuana item recall is required?

- If CCD or DPHHS determines that a marijuana item recall is required, the affected licensee shall:
 - **Immediately** notify registered cardholders and other licensees that received the affected product.
 - **Immediately** issue a press release or other appropriate public notification to inform customers of the recall and identifying information about the affected product recalled.
 - Provide CCD with a copy of the press release or other appropriate public notification.
 - Post on its own website (licensee), if applicable, information about the recall and the affected product.
 - Perform a causation analysis to determine the issue or issues leading to the recall and provide CCD with a <u>corrective action</u> <u>report</u> and <u>preventative action report</u>, as both are defined by the Department of Public Health and Human Services, which details how the affected licensee plans to correct and prevent future recalls.

What should the affected licensee do with remaining product from a marijuana product that has been recalled?

• An affected licensee must coordinate with the CCD for destruction of the affected marijuana product(s) and allow CCD to oversee its destruction.

If a marijuana item is recalled, will CCD have information available to the public?

• CCD shall maintain a marijuana recall page on its website of all current marijuana product recalls.

If CCD issues a recall notice, where can it be found on its website?

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- o Navigate to: https://mtrevenue.gov/cannabis/
- o Under Program Resources, click on Cannabis Product Recalls

Program Resources

- Sales Reports
- Licensed Manufacturer List
- Licensed Testing Laboratory List
- Cannabis Control Division Mandatory Signs
- Frequently Asked Questions
- Montana Cannabis Control Administrative Rules
- Cannabis Product Recalls

Cannabis Licenses

Law Enforcement

When does a marijuana item recall close?

• If CCD determines that a marijuana item recall is successful, and the risk to public health and safety is no longer present, CCD shall notify the affected licensee and close the recall.



Resources and Sources:

- Administrative Rules of the State of Montana, ARM 37.107.303-Definitions
- Administrative Rules of the State of Montana. ARM 42.39.312-Marijuana Item Recalls
- o <u>Montana Code Annotated, 16-12-209-Testing Of Marijuana And Marijuana</u> <u>Products</u>