MONTANA
ADMINISTRATIVE
REGISTER

DEPARTMENT OF REVENUE

NOTICE OF PROPOSED RULEMAKING

MAR NOTICE NO. 2026-447.1

Summary

Amendment of ARM 42.39.312 pertaining to Marijuana Recalls

Hearing Date and Time

Monday, June 1, 2026, at 10:00 a.m.

Hearing Information

Auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana

Comments

Comments may be submitted using the contact information below. Comments must be received by Monday, June 8, 2026, at 5:00 p.m.

Accommodations

The agency will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. Requests must be made by Friday, May 15, 2026, at 5:00 p.m.

Contact

Todd Olson, Rule Reviewer - Department of Revenue, Legal Services Office
(406) 444-7905
todd.olson@mt.gov

General Reasonable Necessity Statement

The Department of Revenue (department) proposes amendments to ARM 42.39.312, which governs marijuana and marijuana product recalls. The proposed revisions reflect the department's broadened operational experience with recalls since the rule was implemented in January 2022 and seek to address regulatory deficiencies that compromise both effectiveness and public safety.

Since enactment of the Montana Marijuana Regulation and Taxation Act (MMRTA), industry has increased production volumes, established more complex distribution networks, and the consumer base has broadened. In February 2024, the department also expanded the list of required pesticide testing. As these regulatory and market conditions have evolved, recall procedures and the risks associated with contaminated or improperly tested marijuana products have grown. Robust recall procedures are essential to protecting public health and safety.

As detailed below, the proposed amendments respond directly to: (1) ambiguity regarding which party bears primary responsibility when multiple licensees are involved in a recall; (2) insufficient specificity regarding triggering events of a product recall; (3) lack of mandatory timelines for critical recall actions; (4) inadequate documentation and tracking requirements; and (5) absence of explicit enforcement mechanisms for non-compliance.

In closing, the department contends this rulemaking will improve regulatory clarity, ensure consistent licensee compliance, and strengthen public health and safety protections within Montana's marijuana industry.

Rulemaking Actions

AMEND

The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

42.39.312 MARIJUANA ~~ITEM~~ RECALLS

(1) For purposes of this rule, the following definitions apply:

(a) "~~a~~Affected licensee" means a licensee whose marijuana or marijuana products are subject to a recall. If ~~M~~more than one licensee~~ may be an~~ is affected~~ licensee in~~ by a recall, the licensee that created the affected product shall be considered the affected licensee~~;~~.

(b) "~~a~~Affected product" means marijuana or a marijuana product subject to a recall.

(2) A recall is required when marijuana or marijuana products pose a risk to public health and safety. ~~A recall shall be based on evidence that marijuana or a marijuana product is contaminated or otherwise unfit for human use, consumption, or application.~~ A product is considered to pose such a risk when, including but not limited to, any of the following events happen:

(a) the licensee cannot provide proof that the product meets all required testing standards pursuant to ARM 42.39.614;

(b) the product fails any testing, including research and development testing, and was not successfully remediated and retested pursuant to ARM 42.39.613 and 42.39.614; or

(c) the product has been improperly or invalidly tested.

(3) A licensee, other than a transporter or testing lab licensee, must develop a written recall plan that is accessible to staff and the department and is subject to audit. The recall plan must establish~~es~~ the procedures the licensee will follow in the event of a recall of its product or products. A recall plan must include, at a minimum:

(a) a designated ~~a~~ member of the licensee's staff who serves as the licensee's recall coordinator, identified by name, title, and contact information;

(b) ~~establish~~step-by-step procedures for identifying and immediately isolating the affected product to prevent or minimize ~~its~~ sales, manufacturing, and distribution ~~to customers~~;

(c) ~~establish~~written procedures to either retrieve and destroy affected product or destroy affected product at all licensed locations; and

(d) ~~establish a communications plan to notify those affected by the recall, including~~ communication protocols that include written procedures for:

(i) ~~how the affected licensee will notify registered cardholders and other licensees in possession of affected product; and~~ notifying registered cardholders, consumers, and licensees, known or reasonably believed to be in possession of the affected product, including the method and timing of communications;

(ii) ~~the use of a press release and other appropriate notifications to ensure customers are notified of the recall and affected product information.~~ coordinating secure transport or return of affected product; and

(iii) issuing a press release and other appropriate public notifications to ensure customers are notified of the recall and affected product information. "Other appropriate public notification" includes, but is not limited to, posting information identifying the affected product on the affected licensee's website.

(4) If the department or ~~the Department of Public Health and Human Services~~ an affected licensee determines that a recall is required, an affected licensee shall:

(a) immediately notify ~~registered cardholders and other licensees that received the affected product~~ the department that it has initiated recall efforts;

(b) segregate the affected product located at its licensed premises immediately upon being notified of the recall;

(c) activate its recall plan within 24 hours of initiating a recall or being notified by the department or another affected licensee of the recall;

~~(b)~~(d) ~~immediately~~ issue a press release or other appropriate public notification~~s~~ ~~to inform customers of the recall and identifying information about the affected product recalled~~ identified in (3)(d)(iii) within 48 hours of being notified of the recall;

~~(c) provide the department with a copy of the press release or other appropriate public notification in (4)(b);~~

~~(d) post on its website, if applicable, information about the recall and the affected product; and~~

~~(e) perform a causation analysis to determine the issue or issues leading to the recall and provide to the department a corrective action 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.~~

(e) within 24 hours of activating the recall plan coordinate with other licensees known or believed to be in possession of the affected product for either the affected licensee's retrieval of the affected product or the destruction of the affected product at its current location;

(f) provide the department with weekly progress reports, detailing recall efforts; and

(g) destroy or, if able, remediate the affected product within 30 business days of being notified of the recall.

(5) An affected licensee must ~~coordinate with the department for destruction of the affected product and allow the department to oversee the destruction~~ provide written confirmation and copies of supporting documentation to the department confirming it has fully complied with (4).

(6) ~~An 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 periodically report to the department on the progress of the recall efforts.~~After a recall has been completed, the affected licensee must identify the cause for the recall and detail, in writing, the corrective actions taken to avoid a future recall. If the affected licensee's conclusions and corrections require modification or replacement of the recall plan in (3), then the affected licensee will provide the updated plan to the department within 30 days from its implementation.

(7) ~~If an affected licensee determines that a recall is required, it must immediately notify the department. The affected licensee must then follow the procedures established in (4) through (6).~~An affected licensee must coordinate the destruction of affected product with the department, and the department must be granted an opportunity, in advance, to oversee the destruction process. The destruction of affected product must be recorded in the seed-to-sale tracking system in compliance with ARM 42.39.310.

(8) ~~If the department determines that a recall is successful, and the risk to public health and safety is no longer present, the department shall notify the affected licensee and close the recall.~~An affected licensee must track all affected product and the amount of affected product returned to the affected licensee as part of the recall effort.

(9) The department shall actively maintain a publicly accessible marijuana recall page on its website of all current recalls.

(10) When the department determines that a recall is successful and the risk to public health and safety is no longer present, the department shall notify the affected licensee, in writing, and close the recall.

(11) An affected licensee's failure to comply constitutes a violation of the marijuana laws and may subject the licensee to administrative action.

Authorizing statute(s): 16-12-112, MCA

Implementing statute(s): 16-12-105, 16-12-112, 16-12-209, MCA

Reasonable Necessity Statement

The department proposes to amend the title of the rule to remove the word “item” and the perceived limitation of the marijuana or marijuana products that are subject to recall.

Section (1)- Definitions - The existing rule broadly defines "affected licensee." The proposed amendment is necessary to clarify that when marijuana products pass through multiple licensees, primary accountability still lies with the originating licensee but other licensees may be affected and they must cooperate in the recall. This amendment ensures prompt, coordinated recall responses and eliminates regulatory uncertainty that has compromised prior recall effectiveness.

Section (2) - Recall Trigger Standards - The existing text states too generally that recalls are required when products "pose a risk to public health and safety" based on evidence of contamination or unfitness, without specific triggering criteria. The existing rule's general standard has proven insufficiently specific to ensure consistent application, licensees have disputed whether particular circumstances trigger mandatory recalls, and the department has lacked clear regulatory authority to compel recalls in situations presenting genuine public health risks. The proposed amendment retains the general standard but adds specific, non-exclusive examples of circumstances requiring recalls while preserving flexibility to address unanticipated public health risks.

Section (3) - Written Recall Plan Requirements - The existing text requires licensees to "develop" a recall plan with minimum content requirements. The department's inspection experience has revealed that many licensees maintain inadequate or non-existent recall plans. Some licensees claim to have "developed" plans that exist only conceptually, lack necessary detail, or are inaccessible during actual recall events. The department has also observed that even in instances where licensees have a comprehensive plan, they fail to follow their own process. The proposed amendments strengthen requirements by mandating that licensees "maintain a written recall plan that is accessible to staff and regulators and is subject to audit," with enhanced specificity.

These enhancements are necessary to ensure recall plans are operational rather than theoretical, can be reviewed for adequacy before recalls occur, and provide sufficient detail to guide effective responses during actual recall events. The requirement for accessibility to staff ensures that employees responsible for executing recalls have ready access to necessary procedures, while accessibility to regulators enables proactive audit and verification of preparedness.

Section (4) - Mandatory Recall Actions and Timelines - The proposed amendment substantially restructures and expands recall action requirements with specific timelines by establishing specific, enforceable timelines that balance operational feasibility with public health urgency. The 24-hour activation timeline ensures prompt response while allowing minimal time for initial assessment and coordination. The 48-hour public notification timeline acknowledges the practical need to prepare accurate, comprehensive public communications while maintaining urgency. The weekly reporting requirement enables ongoing departmental oversight and

ensures recalls remain active priorities. The 30-business-day completion deadline creates accountability for timely recall resolution.

Additionally, the new requirement for immediate departmental notification of self-initiated recalls in (4)(a) closes a critical gap in the existing rule. Section (7) addresses licensee-initiated recalls but lacks the comprehensive requirements of department-initiated recalls. The proposed structure applies consistent requirements regardless of who initiates the recall, ensuring uniform public protection.

Section (5) - Written Confirmation and Documentation - The department has encountered significant challenges verifying licensee compliance with recall obligations. Without mandatory written confirmation requirements, the department must rely on follow-up inquiries, reactive verification, and incomplete documentation. This creates enforcement challenges and makes it difficult to confirm recalls have been fully executed. The proposed provision is necessary to: (1) establish clear documentation obligations; (2) shift the burden of demonstrating compliance to regulated parties; (3) create an auditable record of recall completion; and (4) enable efficient departmental verification without extensive follow-up investigation. This requirement serves both regulatory efficiency and public safety by ensuring the department can promptly verify that public health risks have been adequately addressed.

Section (6) - Corrective and Preventative Action Plans - The proposed amendment: (1) consolidates corrective and preventative action requirements into a single plan; (2) removes an outdated reference to the Department of Public Health and Human Services; (3) clearly states the required content (cause identification and preventative action details); and (4) emphasizes implementation of preventative measures. This restructuring is necessary to ensure licensees understand their obligations and focus on preventing recurrence rather than analyzing past failures.

Section (7) - Destruction Coordination and Tracking System Recording - The proposed amendment retains coordination and oversight language but adds a critical requirement: "All destruction of affected products must be recorded in the seed-to-sale tracking system pursuant to ARM 42.39.310." The department has discovered recalled products that were allegedly destroyed but the purported destruction was not recorded in the seed to-sale tracking system, creating compliance verification challenges. Without mandatory tracking system recording, the department cannot verify destruction through standard audit procedures and must rely on separate documentation. The proposed amendment is necessary to integrate recall product destruction into the comprehensive seed-to-sale tracking system, enable automated verification of destruction, prevent potential distribution of recalled products, maintain complete inventory accountability, and ensure consistency with other inventory disposition requirements. This integration strengthens both product tracking and recall accountability.

Section (8) - Product Tracking –The proposed amendment eliminates redundancy with the more specific weekly reporting requirement in (4)(f), improving clarity without reducing substantive obligations.

Section (9) - Department Recall Website - The additional language is necessary to clarify the department's ongoing obligations to transparency and public access and emphasizes the dynamic nature of active recalls affecting product safety.

Section (10) – Closure of a Recall – The department believes that the addition of new (10) provides affected licensees with procedural guidance about the necessary conditions to close out a current recall.

Section (11) - Enforcement Authority - The existing rule text lacks any reference to the department's enforcement authority under the marijuana laws, which creates ambiguity about consequences for non-compliance and has complicated adjudicatory proceedings against non-compliant licensees where licensees failed to maintain adequate recall plans, delayed or failed to execute recall obligations, failed to provide required documentation, and ignored departmental recall directives.

The proposed provision is necessary to explicitly notify regulated parties that recall violations carry enforcement consequences and provide clear regulatory basis for administrative proceedings while preserving enforcement discretion.

Small Business Impact

With regard to the small business impact analysis requirements of 2-4-111, MCA, as amended by HB 592 (2025), the department has analyzed the proposed rule amendments and the group or class of businesses directly affected by this rulemaking, and concludes those impacted small businesses are the testing laboratories, cultivators, dispensaries, or manufacturers of marijuana and marijuana products if they meet the definition of a small business under 2-4-102(13), MCA. As of April 1, 2026, there are 211 cultivators, 143 manufacturers, and two testing laboratory licensees active within Montana.

The department contends that any small business impact directly related to the enhanced product recall and compliance efforts does not arise from the proposed rulemaking, as they are secondary to the public policy goals articulated by the Legislature under the MMRTA. The department also contends that any impacted opponents are taking issue with industry best practices, improved guidance for operating compliant cannabis businesses, and the department's efforts to close operational or legal loopholes that are contrary to the MMRTA.

Documentation of the small business impact analysis is available upon request.

Bill Sponsor Notification

The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

Interested Persons

The Department of Revenue maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request, which includes the name and e-mail or mailing address of the person to receive notices and specifies that the person wishes to receive notice regarding particular subject matter or matters. Notices will be sent by e-mail unless a mailing preference is noted in the request. A written request may be mailed or delivered to the contact person in this notice or may be made by completing a request form at any rules hearing held by the Department of Revenue.

Rule Reviewer

Todd Olson

Approval

Brendan Beatty, Director of Revenue