West Virginia Department of HEALTH
OFFICE OF MEDICAL CANNABIS

Compliance Tip

December 18, 2025

Adverse Event Reporting

Applicable Rule(s): § 64-110-23, § 64-112-18

Definitions:

"Adverse event" means an injury resulting from the use of medical cannabis dispensed at a dispensary. An injury includes physical harm, mental harm, or loss of function.

"Medical cannabis organization" means a dispensary or a grower/processor.

Pursuant to West Virginia Code of State Rules § 64-110-23 & § 64-112-18, adverse events ("AE") reported to a dispensary by a patient, caregiver, or practitioner must also be reported immediately to the Office of Medical Cannabis and the affected grower/processor. Medical cannabis organizations have a responsibility to report, investigate, and determine an appropriate course of action to take to protect public health and safety.

Dispensary Responsibilities:

Dispensaries are required to do the following upon becoming aware of an AE:

- Report the AE to the Office of Medical Cannabis ("OMC") and the affected grower processor.
- Cease dispensing the affected medical cannabis suspected to cause the AE.
- Coordinate the return of the recalled medical cannabis with the grower/processor in the instance of a voluntary, mandatory, or administrative recall.

To ensure that dispensaries are reporting AEs in a timely fashion, dispensary employees **should** be given permission in Metrc by Metrc Admins to access the "Adverse Responses" feature. This feature allows dispensary employees to input AE information reported by a patient or caregiver at the point of sale directly into the electronic tracking system for easy and quick access by the OMC.

Refer to Metrc Bulletin **WV_IB_023: Patient Adverse Responses** to follow steps on how to enable this feature for dispensary employees.

Grower/Processor Responsibilities:

Once notified by a dispensary of a complaint involving a report of an AE, a grower/processor must investigate the complaint to determine if further action is required. If determined there is no

further action required, OMC must be notified of the decision within 24-hours by submission of a written report stating the rationale for not taking further action.

If further action is required, a grower/processor will determine whether a voluntary or mandatory recall of the affected medical cannabis product is needed. Growers/processors are also required to have a recall plan in place and follow all procedures outlined in the recall plan, unless it has obtained written approval from the OMC to deviate from the recall plan.

The following actions apply to voluntary and mandatory recalls:

Voluntary and Mandatory Recall Actions

Voluntary Recall:

- A grower/processor may, at its discretion, recall a product for reasons that do not pose a risk to public health and safety. This is known as a voluntary recall.
- If a voluntary recall is initiated by a grower/processor, the grower/processor must notify the OMC at the time the recall begins.

Mandatory Recall

- If it is discovered by the grower/processor that a condition relating to the medical cannabis grown or processed at its facility poses a risk to public health and safety, a mandatory recall must be made and the grower processor must:
  - Immediately notify the OMC by phone.
  - Secure, isolate, and prevent the distribution of any potentially affected medical cannabis by the condition that remains in the grower/processors' possession.
    - No affected medical cannabis product may be disposed of prior to notifying and coordinating with the OMC to dispose of such product.
  - Ensure to immediately notify the OMC and cooperate with the OMC in the recall of affected medical cannabis product

Patient/Caregiver Recall Notification:

An essential part of the recall plan required by West Virginia Code of State Rules § 64-110-23 is a communication plan to notify patients and caregivers affected by a medical cannabis recall. A grower/processor may utilize press releases or other appropriate notifications to ensure patients and caregivers are notified of a recall of affected medical cannabis product(s).

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Additional Guidance:

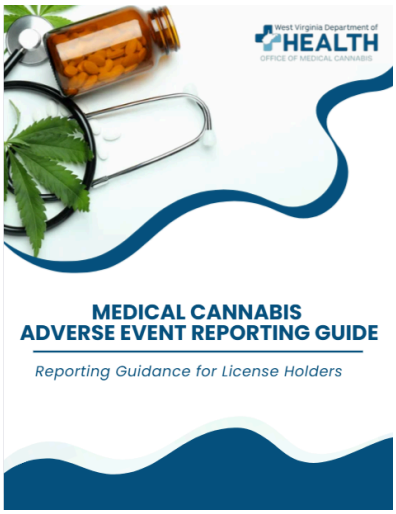
The Office of Medical Cannabis has created an AE reporting guide to help medical cannabis organizations navigate AE reporting requirements. In addition to the reporting guide, the OMC also has created a postcard style infographic that can be placed in patient bags that provides patients with information about adverse events and how to self-report adverse events.

Adverse Event Postcard for Patients & Caregivers:

FRONT

BACK

Medical Cannabis Adverse Event Reporting Guide:



Disclaimer: Licensees are responsible for ensuring they are compliant with applicable statutes and rules. Compliance tips and guidance documents are not intended to be all-inclusive and may not include all relevant statutes or rules. The Office of Medical Cannabis is not able to provide you legal advice. If you have legal questions, consult with an attorney.