MARYLAND MMCC
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Maryland Medical Cannabis Commission
Larry Hogan, Governor • Boyd Rutherford, Lt. Governor • Robert Neall, Secretary

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## Report of Serious Adverse Event to the Commission

**Linthicum, MD** (July 13, 2018) – The Maryland Medical Cannabis Commission (the Commission) is providing this bulletin to remind all licensees, patients, and providers of the mandatory reporting requirements related to any serious adverse event. COMAR 10.62.17 requires a licensee or certifying provider who receives any complaint associated with a serious adverse event to promptly report the complaint to: (1) the Commission, (2) the licensed grower or processor from which the medical cannabis product originated, and (3) the certifying provider caring for the patient. A serious adverse event means "an undesirable experience associated with the use of medical cannabis where the outcome was death, life-threatening, hospitalization, disability or permanent damage, congenital anomaly/birth defect; required intervention to prevent permanent impairment or damage, or any other important medical event."

Within 24 hours of receiving a complaint, a licensee must review the complaint to determine whether it is substantive or a serious adverse event. If the licensee determines a complaint is substantive or a serious adverse event, the licensee must:

1. Promptly report the complaint (1) to the Commission, (2) the grower or processor from which the medical cannabis product originated, and (3) the certifying provider. Complaints must be submitted to the Commission at reporting.mmcc@maryland.gov.
   **Important: Patient Health Information may not be disseminated to other licensees, including the grower or processor from which the medical cannabis product originated, or any third party entities without express, written patient authorization.**
2. Promptly determine the batch number or lot number of the medical cannabis, the medical cannabis finished product, and medical cannabis concentrate that is the subject of the complaint;
3. Investigate the record and circumstances of the production of the batch and lot to determine whether: (a) there was a deviation from the standard operating procedure in the production of the medical cannabis by reviewing production logs; and (b) the sample meets specification by submitting parts of the retention samples of the batch and lot to an independent testing laboratory.

If the investigation reveals that the batch or lot fails to meet specification or that there was a deviation from the standard operating procedure, the licensee shall:

1. Order a recall of all products derived from or included in the batch or lot;
2. Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis products from such a batch or lot of the recall; and
3. Offer and pay reimbursement for any returned medical cannabis.

In any circumstance where a recall is ordered the licensee shall ensure that the recalled medical cannabis is stored and segregated until disposal is authorized by the Commission. All recalled medical cannabis must be disposed within 24 hours of receiving authorization from the Commission to dispose of the recalled material.

Failure to report any serious adverse event to the Commission may result in a fine of up to $5,000 per violation, license suspension or revocation, or both.

This bulletin does not change, remove, or replace any existing regulations under COMAR 10.62.

Joy A. Strand, MHA
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Maryland Medical Cannabis Commission