

4770.4004 SERIOUS ADVERSE INCIDENT REPORTING.**Subpart 1. Reporting requirements.**

A. Persons who must report any serious adverse incident are:

- (1) a registered patient;
- (2) a registered patient's certifying health care practitioner;
- (3) a patient's registered designated caregiver; or
- (4) a patient's parent or legal guardian, if the parent or legal guardian is acting as caregiver.

B. Reporters named in item A must report to the manufacturer where the patient's medical cannabis was dispensed within five business days of the reporter's learning of the incident.

C. A peace officer must report any serious adverse incident relating to overdose and any case of diversion involving an adverse incident within five business days of the incident by calling the general telephone number of the Office of Medical Cannabis. If part of an ongoing investigation, the report must be made within 72 hours of the conclusion of the investigation.

Subp. 2. Manufacturer requirements.

A. Each manufacturer must:

- (1) maintain a toll-free telephone line, which must be available 24 hours a day, seven days a week, that is staffed by professionals who are health care practitioners or state-licensed pharmacists trained in detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem;
- (2) provide a method, approved by the commissioner, for reporting serious adverse incidents online;
- (3) monitor manufacturer-sponsored social media pages and Web sites routinely;
- (4) post instructions for reporting suspected adverse incidents and unauthorized possession on its Web site; and
- (5) make printed instructions for reporting suspected adverse incidents available at all its distribution sites.

B. Each manufacturer must follow up serious adverse incident reports and document all follow-up activities. The manufacturer must continue to follow up reports until the outcome has been established or the subject's condition is stabilized.

C. For adverse incident information collected, the manufacturer must:

- (1) document it on a form provided by the commissioner;
- (2) classify it using Medical Dictionary for Regulatory Activities (MedDRA) coding; and
- (3) store it in a database that complies with general validation principles in the United States Food and Drug Administration's Electronic Records; Electronic Signatures, Code of Federal Regulations, title 21, part 11.

Subp. 3. **Manufacturer reports.**

A. By the fifth day of every month, a medical cannabis manufacturer must compile and submit to the commissioner all adverse incident reports received in the prior calendar month.

B. Within ten business days of learning of an adverse incident, the manufacturer must report to the commissioner:

- (1) any adverse incident that, based on reasonable medical judgment, might have resulted in a serious adverse incident without intervention or medical treatment; or
- (2) a case of diversion resulting in an adverse incident.

C. On August 1 of every year beginning in 2016, each manufacturer must submit to the commissioner a report that contains a summary and a critical analysis of all reported adverse incidents reported to the manufacturer over the past July 1 to June 30.

Statutory Authority: *MS s 14.389; 152.26; 152.261*

History: *39 SR 1760; 40 SR 1599*

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