4770.1850 RECALL PROCEDURES.

A. Each manufacturer must establish a procedure for recalling medical cannabis that has a reasonable probability of causing an unexpected or harmful response in a patient population, despite appropriate use, that outweighs the potential benefit of the medication. This procedure must include:

(1) factors that make a recall necessary;

(2) manufacturer's personnel who are responsible for overseeing the recall; and

(3) how to notify affected parties of a recall.

B. The commissioner may order a manufacturer to undertake a recall of a dried raw cannabis finished good. The commissioner's order must be based on a reasonable suspicion that the finished good presents a risk of causing a serious adverse incident. The commissioner must order the recall of a dried raw cannabis finished good if testing under part 4770.3035 indicates the presence of residues from a crop input prohibited under part 4770.1700 are present in the finished good. A manufacturer must comply and cooperate with any recalls ordered by the commissioner.

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

History: *40 SR 1599; 46 SR 1011*

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