Minnesota Department of Health

OFFICE OF MEDICAL CANNABIS

Office of Medical Cannabis: Manufacturer Fact Sheet

Authority

The Minnesota legislature assigned the Department of Health (MDH) the task of selecting and regulating the activities of two medical cannabis manufacturers. In performing those duties MDH ensures that manufacturers comply with numerous health and safety requirements including those pertaining to medical cannabis production, testing and reporting.

While this fact sheet highlights certain regulatory requirements, the full set of requirements are found in Minnesota Statutes, section 152.29 and Minnesota Rules, parts 4770.0100 to 4770.2800.

Hydro-carbon based Extraction Prohibited

A medical cannabis manufacturer may not use a hydro-carbon based extraction method without the approval of the commissioner of health. Hydrocarbon based extraction methods include the use of butane, hexane and alcohols.

- *The commissioner has not approved any hydro-carbon based extraction method.*

Cultivation and Processing Safety

Cultivation and processing safety regulations include requirements pertaining to sanitation, storage, testing, record keeping and reporting.

Examples of general sanitation requirements include:

- designing production processes to limit contamination;
- employing and documenting biosecurity measures;
- preventing sick employees from performing tasks that might contaminate plant material or medical cannabis;
- establishing specific hygiene practices for employees that handle plant material and medical cannabis;
- maintaining buildings and fixtures in a sanitary condition; and
- identifying potentially harmful chemicals and storing them in a location away from plant material and medical cannabis.

Rules on storage areas for plant material and medical cannabis include requirements that they be:

- clean, orderly and well-ventilated;
- free from bird or any kind of pest infestation; and
- protected against physical, chemical and microbial contamination and deterioration of the product or its container.

Product Quality Assurance Standards

Medical Cannabis manufacturers are also required to develop and implement a quality assurance program to assess the chemical and microbiological composition of the medical cannabis they produce. This assessment includes a profile of the medicine's:

- active ingredients;
- inactive ingredients; and
- contaminants.

Random samples will be tested for all potential contaminants from the cultivation and production processes. Testing to determine shelf life (stability) of each product type is also required. Reserve samples must be retained for at least a year beyond the determined expiration date in case retesting is required.

Minnesota Statutes, 152.25, subd. 1(d) requires that all testing be conducted by an independent lab approved by the commissioner of health. The commissioner evaluates testing labs based upon rigorous criteria established in Minnesota Rules, parts 4770.1900 to 4770.2400.

Inventory records

Medical cannabis manufacturers must implement inventory controls, including:

- maintaining real-time records of its inventory of plant material and medical cannabis;
- keeping daily records of the amounts of cannabis plants growing at the cultivation center; and
- conducting inventory reviews and comprehensive inventories of plant material and medical cannabis.

Manufacturer Reporting Requirements

Manufacturer's must maintain records on virtually all aspects of their business for at least 5 years and make them available to the commissioner upon request.

The types of records that must be maintained include records pertaining to:

- Finances and personnel;
- Sales and distribution of medical cannabis;
- Production including fertilizers and pesticides applied;
- Inventory;
- Product testing;
- Waste disposal; and
- Unaccountable materials.

Compliance Assurance

The Department has broad authority to perform unannounced inspections and have access to all of the manufacturer's facilities and business records. Manufacturers are subject to monetary fines of up to $1000 for violating any relevant regulation in addition to having their registration suspended, revoked or non-renewed.

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