



Department of Public Health, Office of Medical Cannabidiol

Inspection Process Overview: Manufacturers and Dispensaries

Per Iowa Code chapter 124E and rules 641-154.28 and 641-154.52, medical cannabidiol manufacturing facilities and dispensaries are subject to reasonable inspection by the department, a department-approved consultant, or other agency as authorized by Iowa Code chapter 124E and the associated administrative rules, and local laws and regulations. Criteria for inspections may include:

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| Aspects of business operations |
| The manufacturing facility or dispensary |
| Vehicles used for transport or delivery of medical cannabidiol or plant material |
| Financial information and inventory documentation |
| Physical and electronic security alarm systems |
| Other inspections as determined by the department |

This document is part of the Office of Medical Cannabidiol’s compliance education, and is designed to assist the licensee in understanding the inspection process. *Failure to understand these rules could result in a compliance violation affecting your ability to operate your business.* The department’s plans for inspections are as follows:

| Inspection Type | Justification |
|--|--|
| Preliminary, Scheduled Inspections | These inspections are planned to help the licensee stay on schedule to become fully operational by 12/1/18. As facilities are completed and become operational, the department will inspect them for compliance and provide feedback. The department will follow-up, as needed, with aspects that did not pass inspection. |
| Unannounced, Targeted, or Complaint-Driven Inspections | Inspections to check for incompliance, discrepancies in seed-to-sale tracking data, in cases where a specific complaint is filed, or as the licensee updates floor plans or critical systems. |
| Annual Inspections | The department will inspect facilities to monitor for continued compliance with rules. |

Proactive Compliance Inspections

Inspectors will be reviewing licensed premises for compliance with department security, inventory and tracking, and operational requirements. In addition, they may be looking for unapproved alterations to premises or changes to business structures.

Licensees should be ready for inspection at all times; the department is not required to notify licensees in advance of a compliance inspection. Regular rigorous and comprehensive self-auditing of the Office of Medical Cannabidiol's procedures and processes is strongly recommended. Medical cannabidiol licensees should be operating as approved at the time of licensing. Below are some Office of Medical Cannabidiol Program licensee requirements with specific details licensees should be aware of and practicing.

Seed-to-Sale Tracking Requirements

A large focus of compliance efforts will be to determine if licensees are following the mandated tracking requirements. Inspectors will perform inventory checks against the department's records. The failure to keep accurate records, even if unintentional, is considered a violation for a licensee.

The bi-weekly reconciliation requirement for manufacturers under 641-154.27(5) and weekly reconciliation requirements for dispensaries under 641-154.51(3) require that each licensee reconcile inventory in an ongoing fashion. Waste inventory resulting from production, packaging, transportation, dispensing, spoilage, or return should be adjusted in the seed-to-sale tracking software. A manufacturer has 72 hours to notify the department of inconsistencies, while dispensaries have 24 hours.

Video Surveillance

Video surveillance requirements mandate a level of security and accountability for licensees. Although surveillance coverage is reviewed at the time of licensure, changes in operations or alterations to premises may result in changes to the way images are captured. Licensees should review their video coverage periodically to ensure compliance with this requirement. Cameras should capture video continuously or using motion detection, have resolution that can capture identification either live or still, have an embedded date and time stamp, and should continue to operate during a power outage. Furthermore, cameras should not be blocked or obscured in such a way that prevents coverage of any limited access or patient sales area.

Office of Medical Cannabidiol rules require that surveillance cameras capture clear images of any individuals and activity in any limited access area, any consumer sales area, and all entries and exits to the premises. A limited access area includes the surveillance area and any area where medical cannabidiol items are or will be present, including while the items are being moved. This means there should be no area of licensed premises where medical cannabidiol products are present that are not captured on cameras; there should be no "blind spots" between covered areas. Specifically, an individual moving between limited access areas should appear on one camera prior to disappearing from another.

Video Retention

Licensees are required to store camera footage on site within the designated surveillance area. These records must be kept for 60 days and must be easily accessible and retrievable. In addition, camera footage shall be archived in a fashion that ensures authentication and guarantees that the footage has not been altered.

General Security

The security of medical cannabidiol and products on licensed premises is critically important. During all times, medical cannabidiol products must be secured.

For manufacturers, all *Cannabis* and medical cannabidiol items - including seeds and immature plants, plant material, medical cannabidiol, or tanks and vessels used during production must be secured. These secured locations must be in areas designated at initial licensure and monitored by video surveillance.

For dispensaries during operating hours, medical cannabidiol products must be stored in such a way that patients cannot access those items until a sale is completed. This means items should not be displayed on an open counter space within easy reach of a patient in the sales area.

Additionally, manufacturers and retailers are required to maintain visitor logs, logs of all patients and employees who enter restricted access areas, and they must maintain a perimeter intrusion detection system. The department will also check the licensees' personnel identification systems, and inspect for employee identification cards for the employees' names, dates of card issuance and expiration, unique employee identification numbers, and employee photographs.

Packaging and Labeling

All products that are packaged and labeled for sale to a patient must be compliant with the United States Poison Prevention Packaging Act and labeling rules under 641-154.21 and 641-154.46.

All medical cannabidiol products being manufactured or sold to a patient must include the proper type of tamper-evident and child-resistant packaging. All manufactured products must be properly labeled with the information required by rule, including name and address of manufacturer, primary ingredients, directions for use, recommended and maximum dosage by age and weight, instructions for storage, product expiration date, date of manufacture, and lot number. For dispensaries, labels created at the time of sale to patients must include a medical cannabidiol tracking number, date and time of dispensing, name and address of dispensary, patient's registry number, and identifying information.

Please note that this checklist is not all-inclusive, and only designed to give guidance to licensees on critical compliance concerns. For access to the medical cannabidiol program regulations, please visit:
<https://www.legis.iowa.gov/docs/iac/chapter/641.154.pdf>.