

**641—154.1(124E) Definitions.** For the purposes of these rules, the following definitions shall apply:

“*Accredited nonpublic school*” means any nonpublic school accredited by the Iowa state board of education, excluding home schools.

“*Audit*” means a financial review by an independent certified public accountant that includes select scope engagement or other methods of review that analyze operational or compliance issues.

“*Background investigation*” means a thorough review of an entity, owner, investors, and employees conducted by the department of public safety, including but not limited to state and national criminal history records, credit records, and internal revenue service records.

“*Batch*” means a set of cannabis plants that are grown, harvested, and processed together, such that they are exposed to substantially similar conditions throughout cultivation and processing.

“*Batch number*” means a unique numeric or alphanumeric identifier assigned to a batch of cannabis plants by a manufacturer when the batch is first planted. The batch number shall contain the manufacturer’s number and a sequence to allow for inventory and traceability.

“*Biosecurity*” means a set of preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases in crops;
2. Quarantined pests;
3. Invasive alien species;
4. Living modified organisms.

“*Bordering state*” means the same as defined in Iowa Code section 331.910.

“*Cannabis*” means seeds, plants, cuttings, or plant waste material from *Cannabis sativa* L. or *Cannabis indica* used in the manufacture of medical cannabidiol.

“*Crop input*” means any substance applied to or used in the cultivation and growth of a cannabis plant. “Crop input” includes, but is not limited to, pesticides, fungicides, fertilizers, and other soil or medium amendments.

“*Date of expiration*” means one year from the date of issuance of the medical cannabidiol registration card by the department of transportation.

“*Date of issuance*” means the date of issuance of the medical cannabidiol registration card by the department of transportation.

“*Debilitating medical condition*” means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:
  - Severe or chronic pain.
  - Nausea or severe vomiting.
  - Cachexia or severe wasting.
2. Multiple sclerosis with severe and persistent muscle spasms.
3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn’s disease.
6. Amyotrophic lateral sclerosis.
7. Any terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:
  - Severe or chronic pain.
  - Nausea or severe vomiting.
  - Cachexia or severe wasting.
8. Parkinson’s disease.
9. Untreatable pain.

“*Department*” means the Iowa department of public health.

“*Department of transportation*” means the Iowa department of transportation.

“*Director*” means the director of the Iowa department of public health.

“*Dispensary*” means an individual or entity licensed by the department to dispense medical cannabidiol to patients and primary caregivers pursuant to Iowa Code chapter 124E and these rules.

“Dispensary” includes the employees and agents of the dispensary.

*“Dispensary facility”* means any secured building, space, grounds, and physical structure of a dispensary licensed by the department to dispense medical cannabidiol and where the dispensing of medical cannabidiol is authorized.

*“Dispense”* or *“dispensing”* means to supply medical cannabidiol to patients pursuant to Iowa Code chapter 124E and these rules.

*“Disqualifying felony offense”* means a violation under federal or state law of a felony under federal or state law, which has as an element the possession, use, or distribution of a controlled substance, as defined in 21 U.S.C. §802(6).

*“Edible medical cannabidiol products”* means food items containing medical cannabidiol. “Edible medical cannabidiol products” does not include pills, tinctures, oils, or other forms of medical cannabidiol that may be consumed orally or through the nasal cavity that do not contain food or food additives; provided that food or food additives used as carriers, excipients, or processing aids shall not be considered food or food additives.

*“Form and quantity”* means the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

*“Health care practitioner”* means an individual licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery who is a patient’s primary care provider. “Health care practitioner” shall not include a physician assistant licensed under Iowa Code chapter 148C or an advanced registered nurse practitioner licensed pursuant to Iowa Code chapter 152 or 152E.

*“Inspection”* means an on-site evaluation by the department, the department of public safety, or a department-approved independent consultant of facilities, records, personnel, equipment, methodology, and quality assurance practices for compliance with these rules.

*“International Electrotechnical Commission”* or *“IEC”* means an independent, nongovernmental membership organization that prepares and publishes international standards for all electrical, electronic, and related technologies.

*“International Organization for Standardization”* or *“ISO”* means an independent, nongovernmental membership organization and the largest developer of voluntary international standards.

*“Laboratory”* means the state hygienic laboratory at the University of Iowa or other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an ISO-approved accrediting body, with a controlled substance registration certificate from the Drug Enforcement Administration of the U.S. Department of Justice and a certificate of registration from the Iowa board of pharmacy, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol.

*“Lot”* means a specific quantity of medical cannabidiol that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

*“Lot number”* means a unique numeric or alphanumeric identifier assigned to a lot by a manufacturer when medical cannabidiol is produced. The lot number shall contain the manufacturer’s number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of a lot of medical cannabidiol.

*“Manufacture”* or *“manufacturing”* means the process of converting harvested cannabis plant material into medical cannabidiol.

*“Manufacturer”* means an individual or entity licensed by the department to produce medical cannabidiol and distribute it to dispensaries pursuant to Iowa Code chapter 124E and these rules. “Manufacturer” includes the employees and agents of the manufacturer.

*“Manufacturing facility”* means any secured building, space, grounds, and physical structure of a manufacturer for the cultivation, harvesting, packaging, processing, storage, and distribution of cannabis or medical cannabidiol and where access is restricted to designated employees of a manufacturer and escorted visitors.

*“Market withdrawal”* means the voluntary removal of medical cannabidiol from dispensaries and patients by a manufacturer for minor issues that do not pose a serious health threat.

*“Medical assistance program”* means IA Health Link, Medicaid Fee-for-Service, or HAWK-I, as administered by the Iowa Medicaid enterprise of the Iowa department of human services.

*“Medical cannabidiol”* means any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that has a tetrahydrocannabinol level of no more than 3 percent and that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and designated in this chapter.

*“Medical cannabidiol waste”* means medical cannabidiol that is returned, damaged, defective, expired, or contaminated.

*“National criminal history background check”* means fingerprint processing through the department of public safety and the Federal Bureau of Investigation (FBI) and review of records on file with national organizations, courts, and law enforcement agencies to the extent allowed by law.

*“Patient”* means a person who is a permanent resident of the state of Iowa who suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E and these rules.

*“Permanent resident”* means a natural person who physically resides in Iowa as the person’s principal and primary residence and who establishes evidence of such residency by providing the department with one of the following:

1. A valid Iowa driver’s license,
2. A valid Iowa nonoperator’s identification card,
3. A valid Iowa voter registration card,
4. A current Iowa vehicle registration certificate,
5. A utility bill,
6. A statement from a financial institution,
7. A residential lease agreement,
8. A check or pay stub from an employer,
9. A child’s school or child care enrollment documents,
10. Valid documentation establishing a filing for homestead or military tax exemption on property located in Iowa, or
11. Other valid documentation as deemed acceptable by the department to establish residency.

*“Plant material”* means any cannabis plant, cutting, trimming, or clone that has roots or that is cultivated with the intention of growing roots.

*“Plant material waste”* means plant material that is not used in the production of medical cannabidiol in a form allowable under these rules.

*“Primary caregiver”* means a person who is a resident of this state or a bordering state, including but not limited to a parent or legal guardian, at least 18 years of age, who has been designated by a patient’s health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol pursuant to the provisions of Iowa Code chapter 124E and these rules.

*“Primary care provider”* means any health care practitioner involved in the diagnosis and treatment of a patient’s debilitating medical condition.

*“Production”* or *“produce”* means:

1. Cultivating or harvesting plant material;
2. Processing or manufacturing; or
3. Packaging of medical cannabidiol.

*“Public or private school”* means any property operated by a school district, charter school, or accredited nonpublic school for purposes related to elementary, middle, or secondary schools or secondary vocation centers.

*“Recall”* means the return of medical cannabidiol from patients and dispensaries to a manufacturer because of the potential for serious health consequences from the use of the medical cannabidiol.

*“Restricted access area”* means a building, room, or other contiguous area on the premises where plant material is grown, cultivated, harvested, stored, packaged, or processed for sale under control of the manufacturer, and where no person under the age of 18 is permitted.

*“State”* means a state of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

*“Untreatable pain”* means any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.

*“Written certification”* means a document signed by a health care practitioner, with whom the patient has established a patient-provider relationship, which states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

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