

CHEAC Summary

CDPH Medical Cannabis Regulations

[Manufacturing](#)

The California Department of Public Health (CDPH) proposed regulations focus on the manufacturing of medical cannabis throughout California. We encourage members to read the entire document released by CDPH; however, a summary of the most relevant aspects is provided below.

Operational definitions (pages 1-7)

- These include: Adulteration (defined in statute), cannabis product, edible cannabis product, environmental pathogen, infusing, labeling, manufacture, package or packaging, preventive controls, and product identity.

Manufacturing License Classifications (pages 11-12)

- Creates two new license classifications for manufacturing:
 - Type P - entities that only package or repackage medical cannabis products or label or relabel the cannabis product container
 - Type N – manufacturers that produce edible products or topical products using infusion processes, or other types of medical cannabis products other than extracts or concentrates.

Application Requirements (pages 14-18)

- To apply to the state for licensure, applicant must include the number, date of issuance and date of expiration of the local jurisdiction's license, permit or other authorization for the manufacture of medical cannabis products.
- Documentation must include the applicant is in compliance with all local ordinances and regulations or will be by the time CDPH issues a license.

Waiver of Sovereign Immunity (pages 21-22)

- Any applicant or licensee that falls within the scope of a sovereign immunity must conduct all commercial cannabis activity in full compliance with the state laws and regulations governing commercial cannabis activity, including all enforcement provisions.
- Must allow access as required by state statute or regulation to persons or entities charged with duties under state law or regulations governing commercial cannabis activity.

Operations in existence prior to January 1, 2018 (pages 24-25)

- Any applicant operating as a manufacturer on or before 1/1/18 may continue to operate until CDPH approves or denies its application if:
- Submit a completed application by 1/1/18.
- Applicant is operating pursuant to a license, permit or other authorization from a local jurisdiction

- Priority will be given to applicants that demonstrate they were in operation and in good standing with the local jurisdiction by 1/1/16.

Application and license fees (page 26)

- Requires a nonrefundable application fee of \$1,000.
- Fees range from \$2,000 to \$5,000 a year based on gross annual revenues

License Restraints (page 33)

- No applicant for manufacturing may hold a testing or distribution license.

Operational requirements (pages 36-39)

- Every licensee must have in place a Security Plan and have a complete digital video surveillance system in place.

Good manufacturing practices (pages 43-56)

- Written **Personnel** procedures must include:
 - Disease Control
 - Cleanliness including thorough hand washing, gloves, hairnets, prevention of cross contamination.
- Written **Premises** procedures must include:
 - Kept in condition that prevents contamination of components and cannabis products, including proper storage of equipment, provision and maintenance of waste treatment systems
- **Facility Construction & Design** requirements include:
 - Adequate precautions to reduce potential for allergen cross-contact and for contamination of cannabis products
 - Protection for production ingredients
 - Adequate lighting for handwashing areas, among others
 - Adequate ventilation or control equipment
- Written **Sanitary** operations must include:
 - Ensure physical facilities on premises are maintained in a manner to prevent cannabis products from becoming adulterated
 - Ensure that cleaning and sanitation of utensils and equipment protect against allergen cross-contact and contamination of cannabis products or product components
- **Sanitary Facilities and controls** should cover:
 - Water supply, plumbing, sewage disposal, toilet facilities, hand washing facilities, and rubbish disposal
- **Equipment & Utensils** should be designed to protect against adulteration and allergen cross-contact or from contamination by any source

Manufacturing Operations (pages 57-71)

- All licensees must conduct a Hazard Analysis, including biological, chemical, and physical hazards
 - Upon completion of analysis, must identify & implement preventive controls
- Establish & follow written master manufacturing protocol
- Prepare batch production records
- Establish and implement written procedures on product complaints

Recalls (pages 72-73)

- Establish and implement written procedures for recalling cannabis products
 - Recalled products must be quarantined and then must be disposed of appropriately
 - Licensee must notify CDPH of any recall within 24 hours.

Record Keeping Requirements (page 74)

- Licensees must keep on premises at all times and must make available to CDPH and any enforcement agency upon request:
 - Valid state license
 - Valid local license, permit, or approval
 - Standard operating procedures
 - Shipping Manifests
 - Employee records

Track & Trace (page 75)

- Licensees must enter into the track and trace database:
 - Receipt of cannabis material
 - Transfer to or receipt from another licensed manufacturer of CP for further manufacturing
 - Transfer to a distributor

Other Responsibilities (pages 76-82)

- Licensees must establish and maintain written standard operating procedures
- Any licensee producing edible cannabis products must have all personnel who prepare, handle or package edible products successfully complete an accredited food handler course within 90 days of employment & then every three years.
- Licensees must establish and implement written inventory control plan
- Licensees must dispose of cannabis waste, defined as solid waste that contains cannabis, but has been made unusable and unrecognizable.
- Licensees must maintain records regarding waste material including on disposal of waste.

Cannabis Product Standards (pages 83-86)

- Licensees are prohibited from infusing alcoholic beverages.
- Prohibitive additives include nicotine and caffeine

- No cannabis product can be made of potentially hazardous food (including juice and perishable bakery products)
- Licensees are prohibited from applying cannabinoids to commercially available candy or snack food items.
- Edible cannabis products are limited to ten milligrams of THC per serving
- Edible cannabis products shall be homogenized to ensure uniform disbursement of cannabinoids throughout the product

Labeling requirements (pages 87-93)

- All information required to be listed on the label must be in English
- Primary panel labeling requirements include identity of the product, the words “cannabis-infused, the cannabis product symbol, the THC content for the package in its entirety
- Labels must also include the licensees name and contact information, date of manufacture, a list of all product ingredients, amounts in grams of sodium, sugar, carbohydrates, and total fat per serving, the lot number, a unique identifier, an expiration date and the following statements:
 - Schedule I Controlled Substance
 - Keep out of reach of children in animals (bold print)
 - For medical use only
 - If pregnant or breastfeeding, consult a physician prior to use
 - The intoxicating effects of this product may be delayed by up to two hours
 - This product may impair the ability to drive or operate machinery, please use extreme caution.

Labeling restrictions include:

- Content that is or designed to be attractive to individuals under the age of 21 (cartoons, images, characters, or phrases popularly used to advertise to children, any imitation of candy packaging or labeling, claims of health benefits or other physical benefits.
- All products must be marked, stamped or otherwise imprinted with the cannabis product symbol (upside down red triangle stamped with THC!)

Packaging (page 94)

- Must protect from contamination, tamper-evident (cannot be opened without obvious destruction of the seal), child-resistant (significantly difficult for children under five years of age to open.

Inspections & Enforcement (page 95)

- Allows the Department & its inspectors or agents to conduct on-site inspections prior to issuing a license or renewing a license and to conduct investigations.
- Allows the Department and its inspectors or agents free access “at reasonable times” to manufacturing premises, storage areas, records, production processes, labeling and packaging processes including all pertinent equipment, raw material, finished and unfinished materials, containers, packaging, and labeling.