

# MEDICINAL AND ADULT-USE CANNABIS REGULATION AND SAFETY ACT REGULATIONS OVERVIEW

# **ALL BUREAU LICENSES**

- Temporary License Allows for Operations while Annual License Application is Pending
  - A temporary license allows a business to engage in commercial cannabis activity for a period of 120 days.
  - The Bureau can only issue a temporary license if the applicant has a valid license, permit, or other authorization issued by the local jurisdiction in which the applicant is operating.

#### Annual Licenses

- All commercial cannabis activity shall be conducted between licensees.
- There is no specific number limit to the licenses that may be held by an applicant. There is no restriction on the types of cannabis licenses a person can hold, except a person who holds a testing laboratory license is prohibited from licensure for any other commercial activity.

 An annual license issued by the Bureau is valid for 12 months from the date of issuance and may be renewed annually.

## **■** Local Compliance Verification

- If the applicant provides a local license, permit, or other authorization, the Bureau will contact the local jurisdiction to verify the information and will allow at least 10 days for the jurisdiction to respond before issuing the license, unless a response is received from the local jurisdiction sooner.
- If an applicant for an annual license does not provide a local license, permit, or other authorization, the Bureau will contact the local jurisdiction to verify that issuing the license would not violate a local ordinance or regulation. After 60 days, if there is no acknowledgement by the local jurisdiction, the Bureau shall presume the applicant is in compliance and may issue a license.

# MEDICINAL AND ADULT-USE CANNABIS REGULATION AND SAFETY ACT REGULATIONS OVERVIEW

## ■ License Type Designation

 Licensees must hold an A-license to engage in adult use commercial cannabis activity and an M-license to engage in medicinal commercial cannabis activity. The exception is testing laboratories, which may test cannabis goods for both license types.

## Ownership

- An owner is a person who: holds at least 20 percent aggregate ownership interest in a commercial cannabis business; is a chief executive officer or member of the board of directors of a non-profit; or will be participating in the direction, control, or management of the entity applying for licensure.
- Owners must submit fingerprints, information regarding any criminal convictions, and disclose whether they have a financial interest in any other commercial cannabis business licensed under MAUCRSA.

# Priority Licensing

- Priority application review will be provided for annual licenses only.
- To be eligible for priority licensing, an applicant must be able to demonstrate that the business was in operation and in good standing with the local jurisdiction by September 1, 2016.

### Premises Requirements

- Applicants must identify the designated structure(s) and real property under the control of the applicant or licensee where commercial cannabis activity will take place.
- Each license must have a separate licensed premises, unless all of the following requirements are met:
  - A licensee holds both an M-license and A-license for the identical type of commercial cannabis activity;
  - The licensee holding both licenses is identical in name, business formation, and ownership;
  - The licensee only conducts one type of commercial cannabis activity on the premises;
  - All cannabis and cannabis products are clearly marked with an "M" or "A": and
  - Records are kept separately for each license and clearly indicate the records are related to the M-license or A-license.
- Security measures are required at licensed premises. Measures include:
  - Employee badges, designated limited-access areas, and security personnel.



# MEDICINAL AND ADULT-USE CANNABIS REGULATION AND SAFETY ACT REGULATIONS OVERVIEW

- 24-hour video surveillance for areas containing cannabis and cannabis products as well as all entryways and exits. Retailers must also have video surveillance in point-of-sale areas and security personnel.
- Alarm systems, commercial grade locks, and secure storage of cannabis and cannabis products.
- All employees of the licensee must be at least 21 years old.

#### Cannabis Waste

- Cannabis waste must be contained in a secured waste receptacle or secured area on the licensed premises.
- Licensees may not sell cannabis waste and must comply with all applicable waste management laws.

# Labor Peace Agreement

Applicants for a license with more than 20 employees must either:

 (1) attest that they have entered into a labor peace agreement and that they will abide by the terms of the agreement, and provide a copy of the agreement to the Bureau, or
 (2) provide a notarized statement indicating the applicant will enter into and abide by the terms of the labor peace agreement.

# ADDITIONAL REQUIREMENTS BY LICENSE TYPE

Distributor License – Arrange for testing, check for appropriate packaging and labeling, collect taxes, transport cannabis and cannabis products, and may act as a wholesaler. All transportation shall be conducted by distributor licensees and their direct employees.

- Cannabis and cannabis products
  must pass through a distributor prior
  to being sold to customers at a retail
  establishment.
- Distributors must arrange for the laboratory testing and quality assurance for cannabis and cannabis products.
- Distributors may package and label cannabis (dried flower) but may not package cannabis products pursuant to the distributor license.

Distributor Transport-Only License – A distributor can choose to be a Transport Only Distributor, which transports only its own cannabis and cannabis products, or transports for other licensees, but does not perform any of the other functions of a distributor. Transportation to retail licensees is prohibited by this type of license, unless the licensees are transporting immature plants and seeds from a nursery to a retailer.

# MEDICINAL AND ADULT-USE CANNABIS REGULATION AND SAFETY ACT REGULATIONS OVERVIEW

# Additional Transport Requirements for All Distributors

- Cannabis goods may only be transported in a vehicle or trailer, must not be visible from outside of the vehicle, and must be kept in a locked box, container, or cage that is secured to the commercial vehicle or trailer.
- Transport vehicles must be equipped with alarm systems and remain secure at all times.
- Packages or containers holding cannabis goods may not be tampered with, or opened during transport.
- No vehicle or trailer containing cannabis goods shall be left unattended in a residential area or parked overnight in a residential area.
- All transports must have a shipping manifest with specific information about the cannabis and cannabis products being transported. The shipping manifest must identify the licensee shipping, the licensee transporting, and the licensee receiving the shipment.

**Retailer License** – Sell cannabis and cannabis products to customers, often referred to as dispensaries.

 Retailers are not allowed to package or label cannabis or cannabis products on the premises. All cannabis or cannabis products sold at a retailer must be packaged and labeled before arriving at the retail premises, except during the transition period.

- Retailers may only sell and deliver cannabis goods between the hours of 6 a.m. and 10 p.m.
- Before leaving the retail premises, cannabis purchases must be placed in an opaque exit package.
- Deliveries must be made in person by a direct employee of the licensee to a physical address within the State of California.
- Delivery vehicles may not contain more than \$3,000 of cannabis product at any time. The retailer must be able to immediately locate all delivery vehicles.

Microbusinesses License – Microbusiness licensees must engage in at least three of the following commercial cannabis activities: cultivation (less than 10,000 square feet), manufacturing (Level 1, Type 6), distribution, and retail.

A holder of a microbusiness license
may only engage in the commercial
cannabis activity requested in the
license application and approved by
the Bureau. If a microbusiness licensee
wants to engage in additional commercial
cannabis activity after the license is
issued, the licensee shall submit an
application to the Bureau identifying the
requested changes and providing all
information required for an application
for the commercial cannabis activity the
licensee wants to conduct.

# MEDICINAL AND ADULT-USE CANNABIS REGULATION AND SAFETY ACT REGULATIONS OVERVIEW

 Licensees will be required to comply with the rules and regulations applicable to the commercial cannabis activities the microbusiness is conducting.

**Testing Laboratory License** – Test cannabis and cannabis products.

## Provisional Testing Laboratory License

- Testing laboratories that meet all other requirements, but are awaiting ISO (the joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission) 17025 accreditation may obtain a provisional license.
- Provisional licenses expire 12 months after issuance.
- The Bureau may renew the provisional license for an additional 12 months if the laboratory's ISO 17025 accreditation application is still pending.

## Sampling

- Laboratory personnel will take samples from harvest batches and cannabis product batches to be tested. Harvest batches may not exceed 50 pounds. Samples collected from batches weighing more than 50 pounds will be deemed invalid.
- Samplers must follow requirements pertaining to minimum sample sizes, minimum sample increments, transportation and storage of samples, and documentation of all sampling activity.

 Samples received by a laboratory that do not adhere to the requirements will be rejected.

### Tests Performed

- Testing laboratories will be required to perform testing on cannabis goods to measure the following:
  - Cannabinoids;
  - Foreign material;
  - Heavy metals;
  - Microbial impurities;
  - Mycotoxins;
  - Moisture content and water activity;
  - Residual pesticides;
  - Residual solvents and processing chemicals; and
  - Terpenoids.
- Edible cannabis products that contain more than one serving per unit will be tested for homogeneity to ensure consistent concentrations of tetrahydrocannabinol (THC) or cannabidiol (CBD).

# Certificate of Analysis

 After testing is completed, the laboratory will generate a certificate of analysis that contains the results of the testing and whether the tested batch passed or failed.



# MEDICINAL AND ADULT-USE CANNABIS REGULATION AND SAFETY ACT REGULATIONS OVERVIEW

- Batches that pass testing may be sold to customers via retailers.
- Harvest batches or cannabis product batches that fail testing may be additionally processed for remediation, with the exception of edibles. A batch may only be remediated twice. If the batch fails after a second remediation attempt and second retesting, the entire batch shall be destroyed.

## Quality Assurance and Quality Control

 Testing laboratories are required to develop and implement a quality assurance program that is sufficient to ensure the reliability and validity of the analytical data produced by the laboratory.

## Phase-In of Required Types of Testing

- The required tests for cannabis will be phased in throughout 2018.
- Cannabis harvested on or after January 1, 2018, and cannabis products manufactured on or after January 1, 2018, will be tested for potency, contaminants with a high public health risk, and contaminants that the industry is largely already testing for.
- Cannabis harvested on or after
  July 1, 2018, and cannabis products
  manufactured on or after July 1, 2018,
  will be tested for moderate relative
  health risks compared to the group
  above and contaminants that are
  currently largely not tested for.

Cannabis harvested on or after
December 31, 2018, and cannabis
products manufactured on or after
December 31, 2018, minor relative
health risks compared to the group
above and contaminants that are
seldom or not tested for.

# TRANSITION PERIOD

- To support a smooth transition of businesses into a newly regulated market, beginning January 1, 2018 and before July 1, 2018, licensees may do the following:
  - Conduct business with other licensees irrespective of the M or A designation on their licenses.
  - Transport cannabis goods that do not meet the labeling requirements (prescribed by MAUCRSA or the California Department of Public Health) if a sticker with the appropriate warning statement is affixed.
  - Sell cannabis goods held in inventory that are not in child-resistant packaging if they are placed into child-resistant packaging by the retailer at the time of sale.
  - Sell cannabis products that do not meet the THC limits per package established by the State Department of Public Health.



# MEDICINAL AND ADULT-USE CANNABIS REGULATION AND SAFETY ACT REGULATIONS OVERVIEW

- Sell and transport cannabis goods that have not undergone laboratory testing if a label stating that they have not been tested is affixed to each package containing the goods prior to transport by a distributor or prior to sale if held by a retailer.
- Individually package and sell dried flower held in inventory by a retailer at the time of licensure.
- Cannabis products held in inventory by a retailer that do not meet the requirements set by the State Department of Public Health for ingredients or appearance may be sold by a retailer.
- Beginning January 1, 2018, licensees shall not transport or sell any edible cannabis product that exceeds 10 milligrams per serving. Adult-use products may not exceed 100 milligrams per package; however, medicinal cannabis products may exceed 100 milligrams per package.

# **ENFORCEMENT**

# Right of Access

 Licensees shall provide the Bureau's investigators, compliance monitors, agents, or employees full access to enter licensed premises; and inspect cannabis or cannabis products in the licensee's possession.

- Review and copy any materials, books, or records in the licensee's possession.
- Failure to cooperate and participate in the Bureau's investigation may result in a licensing violation subject to discipline.
- Prior notice of investigation, inspection, or audit is not required.

# Notice to Comply

- The Bureau may issue a written notice to comply to a licensee for minor violations of MAUCRSA or its implementing regulations, observed during an inspection.
- The notice to comply will describe the nature and facts of the violation, including a reference to the statute or regulation violated, and may indicate the manner in which the licensee must correct the violation to achieve compliance.
- Within 15 calendar days, the licensee may sign and return the notice to comply, declaring under penalty of perjury that the violation was corrected and describing how compliance was achieved. Failure to do so may result in a disciplinary action.

# Minor Decoys

 Peace officers may use a person under 21 years of age to attempt to purchase cannabis goods to ensure that licensees and their employees are not selling cannabis goods to minors.



# MEDICINAL AND ADULT-USE CANNABIS REGULATION AND SAFETY ACT REGULATIONS OVERVIEW

# **■** Disciplinary Actions

- The Bureau may take disciplinary action against any license by way of revocation, suspension, fine, restrictions upon any licensee, or any combination thereof.
- The assessed penalty shall take into consideration: the nature and severity of the violation; evidence that the violation was willful; history of violations of the same nature; the extent to which the person or entity has cooperated with the Bureau; the extent to which the person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation; and the extent to which the conduct is a public nuisance or danger to public safety.
- Any Bureau accusation recommending disciplinary action will be served on the licensee and a hearing will be conducted to determine if cause exists to take action against the licensee.

 An accusation may be terminated by written stipulation at any time prior to the conclusion of the hearing on the accusation.

# ■ Citations and Notices to Comply

- The Bureau may issue citations containing orders of abatement and fines to a licensee or unlicensed person in writing.
- The Bureau may issue a notice to comply to a licensee for violations of the act or regulations observed during an inspection. The licensee may within 15 calendar days return the notice indicating the violation was corrected and how compliance was achieved.





Bureau of Cannabis Control 1625 North Market Boulevard, Suite 202-S Sacramento, CA 95834 (800) 952-5210 For the latest updates, follow the Bureau on social media











# CDFA Cannabis Cultivation Regulations at a Glance

#### **LICENSING**

- License Application Fees. CDFA will charge a one-time fee to review an annual cultivation license application. Application fees are scaled based on the average annual production of the license type and range from \$135 to \$8,655.
- Annual License Fees. The license fee schedule has been updated based on an economic analysis of CDFA costs. License fees are scaled based on the average annual production of the license type and range from \$1,205 to \$77,905.
- Temporary Licenses. Applicants must present a local permit, license, or authorization to be considered for a temporary license, which will allow cultivation before an annual license is issued.
- Processor License. An additional license type not included in the original statute has been added for processors, permitting them to trim, dry, cure, grade, and package cannabis. Processors may not grow cannabis under their license.

#### TRACK-AND-TRACE SYSTEM

- Track-and-Trace System/Requirements. Covers the requirements for licensees and/or designated track-and-trace account managers, including training, registration, plant tagging, and inventory tracking. The track-and-trace system will record the movement of cannabis and cannabis products through the state's supply chain—from cultivation to sale.
- Applicant Track-and-Trace Training Requirement. Requires applicants to complete a training session for the track-and-trace system within 10 days of receiving notice that their complete application has been received and approved by CDFA.

#### RESOURCE MANAGEMENT

- Cannabis Waste Management. Requires licensees to comply with current state
  waste-management laws and include requirements for on-site composting, using
  a waste hauler, or self-hauling.
- Renewable Energy Requirements. Renewable energy requirements allow a phase-in period. Beginning in 2022, licensees will need to provide details regarding energy use and sources. Beginning in 2023, licensees must meet the average electricity greenhouse-gas-emissions intensity required of their local utility provider.

Generator Requirements. Specifies allowable generator types and use restrictions. For example, generators rated at 50 horsepower or greater must demonstrate compliance with California Airborne Toxic Control Measures. Generators rated below 50 horsepower will have to meet compliance measures by 2023.

#### INSPECTIONS/VIOLATIONS

- Inspections, Investigations, and Audits. All inspections, investigations, and audits of the licensed premises shall be conducted during standard business hours or at a time mutually agreed to by the Department and the licensee. For the purposes of this section, standard business hours are 8:00am-5:00pm (Pacific Standard Time). Prior notice of inspection, investigation, or audit is not required.
- Record Retention/Sales Invoice or Receipt Requirements. Governs the maintenance of records and sales invoices for licensees.
- Licensing Actions. Enforcement actions may be taken for any violation(s) of license conditions or requirements. If the licensee holds multiple cultivation licenses, the Department may take any one of, or a combination of, the following actions for all of the licensee's cultivation licenses:
  - Revocation:
  - Suspension for a specified period of time;
  - Issuance of a probationary license with terms and conditions; and
  - Order an administrative hold of cannabis and nonmanufactured cannabis products.
- Administrative Fines. Violation Classes: MINOR (Fine range: \$100 to \$500);
   MODERATE (Fine range: \$501 to \$1,000); SERIOUS (Fine range: \$1,001 to \$5,000).
   Repeat violations may result in an escalation of the violation class.
- Administrative Hold Procedure. Details procedures for establishing administrative holds on cannabis and nonmanufactured cannabis products.

# **EMERGENCY REGULATIONS**

# SUMMARY FOR CANNABIS MANUFACTURING



The California Department of Public Health (CDPH) is one of three state licensing authorities charged with licensing and regulating commercial cannabis activity in California. CDPH is responsible for regulation of the *manufacturing* component of the industry, which it will do through the Manufactured Cannabis Safety Branch.

In November 2017, CDPH released Emergency Regulations that outline the standards and licensing procedures for both medicinal and adult-use commercial cannabis manufacturing and products. These replace the medicinal regulations released in April 2017 developed in response to previous versions of state law.

## Key Components of Cannabis Manufacturing Emergency Regulations

#### **Temporary Licenses**

CDPH will issue temporary licenses that allow a business to engage in commercial cannabis activity. Once issued, these licenses will be valid for 120 days and may be extended for additional periods of 90 days, if the business has submitted a complete annual license application. The application will be available on the CDPH website and can be submitted by mail or email. City or county authorization to conduct commercial cannabis activity must be submitted with the temporary license application. Once the application is received, CDPH will contact the city or county to verify the local authorization, and the office will have 10 days to respond. There is no fee for the temporary license.

#### **Annual Licenses**

Applications for annual licenses will be accepted through an online licensing system that will launch in December 2017. This application will require information on the business, owners and financial interest holders, and operating premises, as well as descriptions of procedures for waste disposal, inventory and quality control, transportation and security. Businesses in operation under the Compassionate Use Act prior to September 1, 2016, will receive priority application review. Applicants must be in compliance with city or county ordinances. During the application review process, CDPH will contact the city or county to verify the local authorization. If the applicant does not provide a copy of their local authorization, the local office will have 60 days to respond. If the applicant includes a copy of their local authorization with their application, the local office will have 10 days to respond.

#### **License Categories & Types**

Anyone conducting commercial cannabis manufacturing must obtain a license from CDPH. Each license issued will have one category and one type.

The two license categories are:

A-License

Cannabis products for sale in the adult-use market

M-License

Cannabis products for sale in the medicinal market

A business may hold both M- and A-Licenses at the same premises as long as separate applications are completed. The four license types are:

Tyne 7

Extraction using volatile solvents (ex: butane, hexane, pentane)

Type 6

Extraction using a non-volatile solvent or mechanical method (ex: food-grade butter, oil, water, ethanol, or carbon dioxide)

Type N

Infusions (ex: using pre-extracted oils to create edibles, beverages, capsules, vape cartridges, tinctures or topicals)

Type P

Packaging and labeling only

#### **Operational Requirements**

Licensees must have written procedures for inventory control, quality control, transportation, security and cannabis waste disposal. Descriptions of these procedures or Standard Operating Procedures (SOPs) must be submitted with the annual license application. Cannabis waste cannot be sold, must be placed in a secured area and be disposed of according to applicable waste management laws.

Good manufacturing practices must be followed to ensure production occurs in a sanitary and hazard-free environment, cannabis products are contaminant free and THC levels are consistent throughout the product and within required limits.

Extractions using CO2 or a volatile solvent must be conducted using a closed-loop system, certified by a California-licensed engineer. Volatile, hydrocarbon-based solvents must have at least 99% purity. Finally, volatile solvent, CO2 and ethanol extractions must be certified by the local fire code official.

#### **Product Standards and Prohibited Products**

Products cannot be infused with nicotine or alcohol or have added caffeine. Edible products cannot be shaped like a human, animal, insect, or fruit. Some potentially-hazardous foods, such as meat and seafood, and other products requiring refrigeration, are prohibited for sale as cannabis products. Juice and dried meat made in accordance with requirements are allowed. Perishable ingredients, such as eggs and milk, may be used as long as the final product meets regulatory standards.

#### **THC Limits**

Edible products are limited to a maximum of 10 mg of THC per serving and 100 mg of THC per package. Other cannabis products, such as tinctures, capsules and topicals, are limited to a maximum of 1,000 mg per package for the adult-use market and 2,000 mg of THC per package for the medicinal-use market.

#### Packaging & Labeling

Cannabis product packaging cannot resemble traditionally available food packages, and edibles packaging must be opaque. All manufactured products must be packaged before they are released to a distributor. In addition to these requirements, statute requires that cannabis product packaging not be attractive to children and be tamper-evident, re-sealable if the product includes multiple servings, and child-resistant.

Cannabis product labels must include an ingredient list, some nutritional facts and the CDPH-issued universal symbol. The label may not refer to the product as a candy. In addition to these requirements, statute requires that labels not be attractive to individuals under age 21 and include mandated warning statements and the amount of THC content.

#### **Annual License Fees**

Application Fee - Processing fee of \$1,000.00 per license

License Fee – Scaled according to the gross annual revenue of the licensed premises. These fees are intended to cover costs of administering the manufactured cannabis safety program and range from \$2,000 to \$75,000.

#### **Transition Period**

The state licensing authorities have established a transition period, from January 1 until July 1, 2018, to support a smooth transition into a newly regulated market. During this period, product will be allowed to move between A- and M-licensees. Products manufactured prior to January 1, 2018, can be packaged in secondary packaging that is child resistant, and stickers may be used for the government warning statement and amount of THC/CBD per serving. All products manufactured on or after January 1, 2018 must meet THC limits and product restrictions.

#### **Shared Manufacturing Facilities**

CDPH is currently developing an additional license type, Type S, which will allow businesses to share facility space. This license type will reduce barriers to entry into the legal, regulated market and ensure that cannabis products are manufactured in clean, regulated facilities. This license type should be ready to be issued in early 2018.

#### Other Laws to Know:

California Business & Professions Code - Includes requirements set forth by MAUCRSA

Emergency Regulations released by the Bureau of Cannabis Control – Includes specific requirements for retailers, distributors, third-party testing laboratories and microbusinesses

Emergency Regulations released by the CalCannabis Cultivation Licensing – Includes specific requirements for cultivators and the track-and-trace system

Your Local City or County Ordinances



