

# 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:

##### Type 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 CO<sub>2</sub> 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, CO<sub>2</sub> 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**

California Department of Public Health  
Manufactured Cannabis Safety Branch

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