



# **Cannabis Corporate**

## **LAW FIRM**

Distilling Regulations for Cannabis Manufacturers: An In-Depth Examination of California Cannabis Regulations & the Practical Issues Facing Producers



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# Legal Licensing and Compliance in the Cannabis Industry

- ✳ Categories of Manufacturing Activities and Corresponding License Types
- ✳ Licensing Requirements
- ✳ Standard Operating Procedures
- ✳ Closed Loop System Requirements
- ✳ Select Compliance Issues
- ✳ Packaging & Labeling
- ✳ Taxation





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# Manufacturing Activities and License Types



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# Manufacturing Activities Regulated by CDPH – MCSB

## California Department of Public Health – Manufactured Cannabis Safety Branch

*Cannabis manufacturing covers essentially everything other than flower and prerolls that include only cannabis and kief*  
 Descriptions of license types can be located at 17 Cal. Code Regs §40118

Type 7	Manufacturer 2	Manufacturing sites that produce medical cannabis products using volatile solvents. The State Department of Public Health shall limit the number of licenses of this type.
Type 6	Manufacturer 1	For manufacturing sites that produce medical cannabis products using nonvolatile solvents.
Type N		Edibles, topicals or infusions where the manufacture does not extract the cannabis <i>including prerolls containing anything other than cannabis and kief.</i>
Type S		Shared Use Facilities for infusions, packaging & labeling and extracts using food grade butter or oil
Type P		Packaging and labeling only <i>applies to any cannabis goods (products, cannabis and prerolls</i>

  
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# Manufacturing Licensing Requirements



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# Licensing Requirements for Manufacturers

17 Cal. Code Regs § §40128-40129

- ✳ Disclosure of all Owners and Financial Interest Holders
  - ✳ Live Scan for Owners
  - ✳ Attestation of Completeness and Accuracy under Penalty of Perjury
- ✳ Business Information (17 Cal. Code Regs §40129)
  - ✳ Name and dbas
  - ✳ Primary Contact – this will be used for Metrc Certification
  - ✳ Tax ID
  - ✳ Seller's Permit
  - ✳ Documents on file with Secretary of State
  - ✳ Business Structure
  - ✳ \$5,000 Bond
  - ✳ Designation of Medicinal, Adult-Use or both
- ✳ Property Owner Consent (17 Cal. Code Regs §40131(k))



  
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# Licensing Requirements for Manufacturers

17 Cal. Code Regs § §40128-40129



- ✳ Standard Operating Procedures
- ✳ Premises Diagram (17 Cal. Code Regs §40105, 40131)
- ✳ CEQA Compliance (17 Cal. Code Regs §40132)
- ✳ Type of Manufacturing or Extraction; Type of Products
- ✳ Waiver of Sovereign Immunity for Tribes (17 Cal. Code Regs §40133)
- ✳ Labor Peace Keeping Agreement
- ✳ Evidence of Local Compliance (10 days to respond 17 Cal. Code Regs §40129)
- ✳ Closed Loop Peer Review/UL and Install Certification (17 Cal. Code Regs §40131(l))<sup>1</sup>



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# Regulations – Who is an Owner

## Owner Means:

- ✿ A person with an aggregate interest of 20% or more
- ✿ An individual who will be participating in the direction, control or management of the business.
  - ✿ A general partner of a partnership
  - ✿ Managers or Managing Members of a limited liability company
  - ✿ An officer or director of a corporation
  - ✿ The CEO and members or directors of a nonprofit or other entity



  
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## Regulations – Required Disclosures

- ✿ All owners must submit LiveScan fingerprints to the Department of Justice
- ✿ Financial Interest Holders
  - ✿ Loans (but not banks), investments, any equity interest
  - ✿ Loophole for entity owners closed
    - ✿ Individuals behind any entity must be disclosed absent narrow circumstance



  
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# Manufacturing Licensing Fees

Type of License	Gross Revenue	License Fee <i>\$1,000 app fee included</i>
<b>Tier I</b>	Up to \$100,000	\$2,000.00
<b>Tier II</b>	\$101,000 - \$500,000	\$7,500.00
<b>Tier III</b>	\$501,000 - \$1,500,000	\$15,000.00
<b>Tier IV</b>	\$1,501,000 - \$3,000,000	\$25,000.00
<b>Tier V</b>	\$3,000,001 - \$5,000,000	\$35,000.00
<b>Tier VI</b>	\$5,000,001 - \$10,000,000	\$50,000.00
<b>Tier VII</b>	More than \$10,000,000	\$75,000.00



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# Standard Operating Procedures



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## Inventory Control 17 Cal. Code Regs §40282

- ✳ Written Inventory Control Plan to track location and disposition of all cannabis and cannabis products
- ✳ Inventory Reconciliation **every 30 days**
- ✳ Discrepancies trigger an audit
  - ✳ Notify CDPH within 24 hours if more than 5% discrepancy



  
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## Quality Control 17 Cal. Code Regs §§ 40235-40258

- ✦ Quality Control Program to ensure that cannabis products are not adulterated or misbranded
- ✦ Quality Control Operations include:
  - ✦ Grounds, building, and manufacturing premises per 17 CCR § 40240
  - ✦ Equipment and utensils 17 CCR § 40243
  - ✦ Personnel 17 CCR § 40246
  - ✦ Cannabis product components 17 CCR § 40248
  - ✦ Manufacturing processes and procedures 17 CCR § 40250
- ✦ Master Manufacturing Protocol 17 CCR § 40255
  - ✦ Components used
  - ✦ Weights
  - ✦ Instructions
  - ✦ Anticipated yield
- ✦ Batch Production Records 17 CCR § 40258



  
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## Transportation 17 Cal. Code Regs § 40131(j)(3)

- A description of the transportation process describing how cannabis or cannabis products will be transported into and out of the premises



  
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## Security Plan - 17 Cal. Code Regs § § 40200 and 40205

### ✦ Controlled and Limited Access

✦ *Limited access those areas necessary to complete job duties, and to those time-frames specifically scheduled for completion of job duties, including access by outside vendors, suppliers, contractors or other individuals conducting business with the licensee that requires access to the premises*

### ✦ Commercial Grade Locks and Access Control Systems

### ✦ Alarm System

### ✦ Sign-In/Sign-Out Procedures

### ✦ Security Monitoring System

### ✦ Video Surveillance System

### ✦ Investigation Procedure

### ✦ Loss Prevention and Theft Procedures

### ✦ Inventory and Track and Trace

### ✦ Supervised high risk transactions, such as loading and unloading product

### ✦ Employee storage areas for personal belongings



  
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## Waste Management 17 Cal. Code Regs § 40290

- ✳ On Site Secure Waste Receptacle
- ✳ Waste must be outside its packaging, unrecognizable and unusable
- ✳ Entered into Track and Trace (Metr) Cannabis
- ✳ May be collected from a licensee in conjunction with a regular organic waste collection route used by:
  - ✳ Local agency
  - ✳ Waste hauler franchised or contracted by the local agency
  - ✳ Private waste hauler permitted by the local agency
- ✳ Self Hauled (to a fully manned facility, compost site, etc.)



  
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# Closed Loop and Ethanol Systems



## **Closed Loop Systems** 17 Cal. Code Regs §40225

## **Ethanol Systems** 17 Cal. Code Regs §40223

- ✳️ CO2, volatile solvent, hydro carbon, CFC or other fluorinated gas systems must be closed loop designed to recover the solvents.
- ✳️ Commercially manufactured
- ✳️ Certified by CA Engineer as commercially manufactured as safe, built to code and using by:
  - ✳️ The American Society of Mechanical Engineers (ASME)
  - ✳️ American National Standards Institute (ANSI)
  - ✳️ Underwriters Laboratories (UL)
  - ✳️ The American Society for Testing and Materials (ASTM)
- ✳️ Fire Code and Fire Inspector Approval
- ✳️ Ethanol also requires Fire Approval



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# Select Compliance Issues & Restrictions



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## Prohibited Products and Ingredients 17 CCR §40300, 40305 -40308

### ✿Alcohol

- ✿Except orally-consumed product that contains more than 0.5% alcohol by volume as an ingredient

- ✿Maximum 2 oz bottle and must have dropper

- ✿Non-Cannabinoids that increase potency, toxicity, or addictive

- ✿Any cannabis product that must be held at or below 41 °F

- ✿Except beverages and butter

- ✿Dairy products



  
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## Regulations – Quantity Restrictions 17 CCR §40315

Product Type	Medicinal Limit	Adult-Use Limit
Edibles	10 mg THC per serving 500 mg THC per package	10 mg THC per serving 100 mg THC per package
Concentrated Cannabis Topicals Extractions Wax Shatter Cartridges	2,000 mg THC	1,000 mg THC

  
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## Additional Compliance Issues

- ✱ Submit to BCC Sampling Requests 17 CCR §40292
- ✱ Complaint Handling 17 CCR §40295
- ✱ Recalls 17 CCR §40297
- ✱ Failed Batches 17 CCR §40330
- ✱ On Site Record Keeping 17 CCR §40330
- ✱ Track & Trace 17 CCR §40510



  
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# Packaging & Labeling



## Labeling 17 CCR §40403

- ✳ Flower Packaging 17 CCR §40330
- ✳ Primary Panel Requirements 17 CCR §40405.
- ✳ Edibles 17 CCR §40406
- ✳ Informational Panel 17 CCR §40408
- ✳ Cannabinoid Listing 17 CCR §40409
- ✳ Restrictions 17 CCR §40410
- ✳ Universal Symbol 17 CCR §40412
- ✳ AB-1529
- ✳ Anticipated Effects are ok, but not health claims 17 CCR §40411



  
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## Packaging 17 CCR §40415

- ✱ Tamper Evident
- ✱ Resealable if used multiple times
- ✱ Child Resistant 17 CCR §40417
  - ✱ Enforced as of January 1, 2020
- ✱ Universal Symbol on Vape Cartridge
- ✱ Symbol must be black, but can be outlined in another color



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## LABELING REQUIREMENTS

### MANUFACTURED CANNABIS PRODUCTS



Cannabis products must be properly labeled to ensure consumers are informed about what they are purchasing and to prevent unintended use. These guidelines apply to manufactured cannabis.

#### LABELING PLACEMENT

Where does the required labeling go?

Most of the required labeling must be placed on the outer layer of packaging. The outer labeling requirements are divided into two categories, based on the part of the package where it belongs.

- **Primary Panel** – the part of the label most likely to be displayed to the consumer at retail, typically the front or top of the package
- **Informational Panel** – any other part of the label that is not the primary panel

If the product has multiple layers of packaging, you must also include basic labeling on the inner container that holds the cannabis product.

- Inhaled cannabis products (vape cartridges, shatter, wax, etc.) – must include the universal symbol
- Non-inhaled cannabis products (edibles, tinctures, topicals, etc.) – must include the product identity, universal symbol and netweight or volume. Edible products must also include the words "Cannabis-Infused."

What if my package is small and I can't fit all of the required information on the outer layer?

You can use a supplemental label to include some of the required information. Examples include, hang-tags, peel-back labels, and inserts.

Note: QR codes, websites and other methods that separate the information from the product are not acceptable types of supplemental labeling.

#### DOs

- Display information clearly and legibly
- Use English and at least 6 point font
- Ensure all required labeling is displayed on the outer layer of packaging

#### DON'Ts (§40410)

- **California county names** – Unless 100% of cannabis in the product is grown in the county, the name of a California county cannot be included on the label.
- **Cannot be attractive to children** – This includes using cartoons, images popularly used to advertise to children, imitating candy labeling, and using the words "candy," "candies" or a variation, such as "kandy" or "kandeez" anywhere on the label.
- **Cannot include false or misleading information** – This includes anything untrue or unproven, or information that leads consumers to have an inaccurate impression, or the use of the word "organic" anywhere on the label.
- **Cannot make unproven health claims** – Health-related statements, such as claims about a product's ability to treat or cure disease, may not be made unless there is significant scientific agreement and the claims are supported by a totality of publicly-available peer-reviewed evidence. Anecdotal information and preliminary study results do not meet this criteria.  
Note: Health-related statements are heavily regulated by the FDA, and cannabis businesses are not exempt from federal prosecution for misleading health statements.
- **Cannot include a picture of the product (for edible cannabis products only)** – State law required edibles to be in opaque packaging to reduce the risk that a child would be attracted to the product. Photographs or other images of the product cannot be on the label for the same reason.
- **Cannot market the product as an alcoholic beverage** – More information on this label restriction can be found in the Bureau of Cannabis Control regulations §5041.1.

#### FIND MORE HELP ONLINE

Visit the CDPH website for more information on the packaging and labeling requirements:  
[www.cdph.ca.gov/mcsb](http://www.cdph.ca.gov/mcsb)

[www.cannabis.ca.gov](http://www.cannabis.ca.gov)

[www.cdph.ca.gov/mcsb](http://www.cdph.ca.gov/mcsb)

[mcsb@cdph.ca.gov](mailto:mcsb@cdph.ca.gov)

## LABELING REQUIREMENTS

### MANUFACTURED CANNABIS PRODUCTS



#### LABELING CHECKLIST (FOR OUTER LAYER OF PACKAGING)

**PRIMARY PANEL** – the part of the label displayed to consumers at retail, typically the front or top of the package

- ☐ **Product identity** – A generic or common name that describes the product. Examples include chocolate, fruit chew, vape cartridge, lotion, tincture, etc.
- ☐ **Universal symbol** (in black, at least 0.5" x 0.5") – The California symbol that identifies items as containing cannabis. Download the symbol at [www.cdph.ca.gov/mcsb](http://www.cdph.ca.gov/mcsb).
- ☐ **Netweight or volume** (in both metric and U.S. customary units) – The weight or volume of the contents of the package.

Edible cannabis product labels must also include:

- ☐ **"Cannabis-Infused"** – These words must be listed above the product identity, in a bold font and larger text size than the one used for the product identity.

**INFORMATIONAL PANEL** – any part of the label that is not the primary panel

- ☐ **Manufacturer name and contact information\*** – Must be a name listed on the license certificate (either the legal business name or the registered DBA), and their phone number or website
- ☐ **Date of manufacture/packaging\*** – One date may be used. Include month, day and year. (Example: MFG/PKG 02/23/19)
- ☐ **Government warning statement for cannabis products\*** (capital letters and bold font)
- ☐ **UID number** – The unique tracking number issued through Track-and-Trace  
Note: This requirement will begin when you receive your Track-and-Trace login. Do not create a placeholder UID number.
- ☐ **Batch or lot number**
- ☐ **Instructions for use and any preparation needed\*** – For example, the method of consumption or application
- ☐ **List of all ingredients\*** (in descending order by weight or volume) – Include sub-ingredients, if any
- ☐ **Allergens\*** (if applicable) – The word "Contains," followed by a list of any major food allergen in the product. The major food allergens are milk, egg, tree nuts, wheat, peanuts, soybeans, fish or crustacean shellfish. Use the specific food name when disclosing allergens (i.e. "almonds" instead of "tree nuts").
- ☐ **Artificial food colorings\*** (if applicable)
- ☐ **Expiration, use-by or best-by date\*** (if applicable)
- ☐ **"KEEP REFRIGERATED" or "REFRIGERATE AFTER OPENING"** (if perishable after opening)
- ☐ **"FOR MEDICAL USE ONLY"** (if applicable) – Manufacturers must include these words on the label if the product contains a THC concentration that can only be sold in the medicinal market.

Edible product labels must also include:

- ☐ **Sodium, sugar, carbohydrates, and total fat per serving\*** (in milligrams or grams)

**OTHER LABELING** – may be on either the primary or informational panel

- ☐ **Cannabinoid content (in milligrams)** – Cannabinoid content may be added to the label by the manufacturer before testing or on the distribution premises after testing.
  - THC and CBD per package (for all manufactured products)
  - THC and CBD per serving (for edibles and concentrates with designated serving sizes)
  - Any other cannabinoid that makes up 5% or more of the total cannabinoid content (if labeled after testing)

\* Indicates labeling information that may be placed on a supplemental label

#### ADDITIONAL REQUIREMENTS

**Prop 65 Warning (if applicable)** – Proposition 65 requires businesses to provide a clear and reasonable warning before knowingly and intentionally exposing anyone to chemicals that are known to the state to cause cancer or birth defects or other reproductive harm. For more information on Prop 65 and applicable requirements, visit <http://oehha.ca.gov/proposition65>.

**CRV Recycling (for beverages, if applicable)** – Beverage manufacturers are responsible for labeling qualifying beverage containers with recycling information. For more information, visit <http://www.calrecycle.ca.gov/bevcontainer>.

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[mcsb@cdph.ca.gov](mailto:mcsb@cdph.ca.gov)

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# PACKAGING REQUIREMENTS

## CANNABIS AND CANNABIS PRODUCTS



The Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) includes basic requirements for how cannabis and cannabis products must be packaged before sale. These guidelines apply to all cannabis flower, pre-rolls and manufactured cannabis products sold within California.

### PACKAGING CHECKLIST

- ☐ **Tamper Evident** – A consumer knows if the package has been opened.  
*Example: a plastic seal, a sticker across the lid that is ripped when opened, a jar with a lid that pops up after opening, etc.*
- ☐ **Child Resistant** – The package is designed to be difficult for children under five years of age to open. See below for more information about what qualifies as child resistant.
- ☐ **Resealable** (for products with multiple uses) – The package can be closed after each use.  
*Example: a lid, adhesive closure, box top closure, etc.*
- ☐ **Opaque** (for edibles only)\* – The package is not transparent; consumers cannot see the product through the packaging.  
*\*Amber-colored bottles are considered opaque.*  
*\*Opaque bottles used for beverages may use a single, vertical, clear strip less than 0.25" wide to indicate serving sizes.*

### DOs

- Cannabis flower may be packaged by a cultivator, manufacturer or distributor. Manufactured cannabis products must be packaged and labeled by the manufacturer prior to transfer to a distributor as finished products.
- Protect products from contamination and exposure to any toxic or harmful substances
- If a product has multiple layers of packaging, the packaging requirements can be fulfilled using any one of those layers.

### DON'Ts

- Cannot imitate packaging used for products typically marketed to children
- Cannot imitate packaging used for non-cannabis food products

### CHILD-RESISTANT PACKAGING (CRP)

State law requires all cannabis and cannabis products to be in child-resistant packaging. Until December 31, 2019, a child-resistant exit package, used by a retailer at the time of sale, may be used to fulfill the CRP requirement. Beginning January 1, 2020, every individual product must be in a child-resistant package.

#### What qualifies as child-resistant packaging?

- Packages that have been certified as child-resistant, in accordance with the federal Poison Prevention Packaging Act (PPPA, 16 CFR §1700.1)
- A bottle sealed with a pry-off metal crown bottle cap
- Plastic packaging that is at least 4 mils. thick and heat-sealed without an easy-open tab, dimple, corner or flap

#### Types of CRP:

- **Single Use** ("Initial CRP") – the package is initially child-resistant, but once opened, it is no longer child-resistant. If used, the package's label must say "This package is not child-resistant after opening."
- **Multiple Use** ("Lifetime CRP") – the package maintains its child-resistance throughout the life of the package. It can be opened and closed, but still remains child-resistant.

#### WHAT REQUIRES INITIAL CRP?

- Flower and flower-only pre-rolls
- Inhaled concentrates (infused pre-rolls, vape cartridges, shatter, wax, etc.)
- Topicals
- Single-serving cannabis products

#### WHAT REQUIRES LIFETIME CRP?

- Edibles
- Orally-consumed concentrates (tinctures, capsules, etc.)
- Suppositories

*NOTE: A package containing multiple servings is not required to be in lifetime CRP if each individual serving is in child-resistant packaging.*



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# Taxes



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## Role of the Distributor in Tax Collection

- ✱ Distributor collects cultivation tax from cultivator and passes it to the manufacturer
  - ✱ 9.25 per dry ounce of flower
  - ✱ 2.75 per dry ounce of trim
- ✱ **Manufacturer is responsible for passing the tax to the distributor that takes the cannabis product to retail (or to another manufacturer)**



  
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