

Manufactured Cannabis Training

Understanding Regulations and State Licensing

California Department of Public Health
Manufactured Cannabis Safety Branch



Today's Informational Session

- State Laws & Regulations
- State Cannabis Licensing Authorities
- Regulations for Cannabis Manufacturing
- Temporary License Application Process
- Annual License Application Process
- After You're Licensed
- Q&A



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State Cannabis Offices



Bureau of Cannabis Control (Bureau)

Retailers
Distributors
Testing Labs
Microbusinesses



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Manufactured Cannabis Safety Branch (MCSB)

Manufacturers



CA Department of Food & Agriculture

CalCannabis Cultivation Licensing

Cultivators
Track-and-Trace



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State Cannabis Law

- 1996 Compassionate Use Act
 Proposition 215
- 2015 Medical Cannabis Regulation & Safety Act (MCRSA)
 AB 266, AB 243, SB 643
- 2016 Adult Use of Marijuana Act (AUMA)
 Proposition 64
- 2017 Medicinal and Adult-Use Cannabis Regulation
 & Safety Act (MAUCRSA)
 SB 94, AB 133



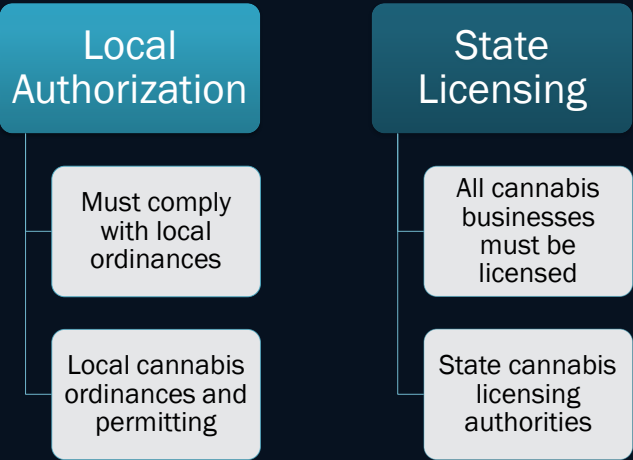
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Principles of MAUCRSA



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Dual Licensing Structure



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State Regulations

- Emergency Regulations
 - Released by each state licensing authority
 - Outline requirements for specific aspects of commercial cannabis market
- Permanent Regulations
 - Rulemaking process
 - Early 2018



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California Track-and-Trace



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MCSB EMERGENCY REGULATIONS

WHAT MANUFACTURERS
NEED TO KNOW



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Role: Protect public health by
promoting product and
workplace safety



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- Regulations
- Licensing
- Compliance



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Cannabis Manufacturing

Extraction – separating cannabinoids from cannabis plant material

Infusion – using plant material or concentrates to create a cannabis product

Packaging and Labeling - putting finished cannabis products into a container and/or marking them for sale



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License Categories and Types

License Categories: **M** (Medicinal) or **A** (Adult-use)

License Types:

Type 7	• Extraction: Volatile Solvents
Type 6	• Extraction: Non-volatile Solvents, Mechanical Methods
Type N	• Infusions
Type P	• Packaging & Labeling Only



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Operational Requirements

- Good Manufacturing Practices
 - Clean, sanitary work environment
 - Control of hazards
- Cannabis Product Safety
 - Free of contaminants
 - Uniform THC levels
- Chemical Extraction Safety
 - Must adhere to local fire code and restrictions



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Cannabis Product Standards

- Product Restrictions
 - Prohibited Additives
 - Prohibited Products
 - Ingredients vs. Final Products
 - Product Shapes
- Requirements for Edibles: Servings



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THC Limits

Edibles

- 10 milligrams per serving
- 100 milligrams per package

Other Products

- 1000 milligrams per package (adult-use)
- 2000 milligrams per package (medicinal)



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Packaging

Cannot resemble traditional food packaging

Opaque packaging (Edibles)

Must be packaged before release to distributor

Must be tamper evident and child resistant

Must be re-sealable, if there are multiple servings



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Labeling

Primary Panel

- Includes product identity, THC content, universal symbol

Informational Panel:

- Includes list of ingredients, warning statement, UID



May not refer to product as candy

Cannot be attractive to children



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State Licensing

Begins January 1, 2018

Temporary Licenses

- Valid 120 days
- May be extended for 90 day periods
- Submit via email or mail
- Need explicit local authorization

Annual Licenses

- Valid 1 year
- Online application process
- Must be “in compliance” with local jurisdiction



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TEMPORARY LICENSE

APPLICATION REQUIREMENTS
AND PROCEDURES



Temporary License Application

- One page form
- Available on MCSB website
- Submit via email or mail with local authorization

SECTION A – LICENSE TYPE (Check all that apply)

☐ Medicinal (M) ☐ Adult-Use (A)

SECTION B – APPLICANT INFORMATION

First Name

Last Name

Title

Phone Number

Email Address

SECTION C – BUSINESS INFORMATION

Legal Business Name (as registered with the California Secretary of State) (Add Name (SSE))

Principal EIN

Working Address

City

State

Zip

County

SECTION D – PREMISES INFORMATION

Physical Address of Manufacturing Premises

City

State

Zip

County

SECTION E – OPERATIONAL ACTIVITIES (Check all that apply for the premises listed in Section D)

Product Types	M	A	Activities	M	A	Extraction Methods	M	A
Edibles			Extraction			Butane/Propane/Propene		
Concentrates			Infusion			EtOH		
Topicals			Packaging/Labeling			Carbon Dioxide (CO2)		
Isomerized/Flavored						Water/Food-grade Solvents		
Vape Cartridges						Food-grade Butter/Oil		
Pre-rolls						Mechanical		
Other:								

SECTION F – LOCAL AUTHORIZATION

Local Issuing Authority

Local (SSE) Phone Number

Local Office Email Address

SECTION G – LOCAL AUTHORIZATION ATTACHMENT

☐ A copy of a valid license, permit or other authorization issued by the local jurisdiction that enables the applicant to conduct commercial cannabis activity at the premises listed in Section D.

SECTION H – DECLARATIONS AND SIGNATURE

I declare under penalty of perjury that:

- The information contained within and attached to this application is complete, true and accurate. I understand a misrepresentation of fact is cause for revocation of this application, denial of license or revocation of an issued license.
- I understand that the temporary license is a conditional license that authorizes my business to engage in the commercial cannabis activity described in the application.
- I understand that the issuance of the temporary license shall not entitle the business to hearing or appeal of the decision.
- I understand that the issuance of a temporary license does not obligate the Department to issue a non-temporary license, nor does it create a vested right to either an extension of the temporary license or to the granting of a non-temporary license.
- I understand that I am responsible for keeping and complying with all state laws and regulations governing medicinal and adult-use cannabis manufacturing pursuant to MACRSA and all other applicable laws and regulations, upon issuance of my temporary license. I understand that I am responsible for compliance with subsequent updates to cannabis manufacturing laws and regulations.

Signature

Print Name

Date



Local Authorization

What is a local jurisdiction?

Temporary License Requirement:

- Local authorization to operate a cannabis business
- Examples: Cannabis business permit, letter of acknowledgement, etc.



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How We Process Temporary Applications



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Temporary Licenses

- Temporary Licenses are valid for 120 days
- Once you have your temporary license:
 - Do business only with other licensees
 - Apply for your annual license



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ANNUAL LICENSE

APPLICATION REQUIREMENTS AND PROCEDURES



Annual License Requirements

- Requirements of Operating a Business in CA
 - CA Business Registration
 - CA Seller's Permit
 - Federal Employer ID Number (FEIN)
 - Compliance with city or county ordinances
- Owners and Financial Interest Holders



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Annual License Requirements

- Who is an **Owner**?
 - At least 20% ownership
 - CEO, Nonprofit Board of Directors, Partners, LLC Members, Corporation Officers/Directors
 - Anyone involved in the direction, control or management of the company
- Who is a **Financial Interest Holder**?
 - Less than 20% ownership
 - Not involved in day-to-day business operation



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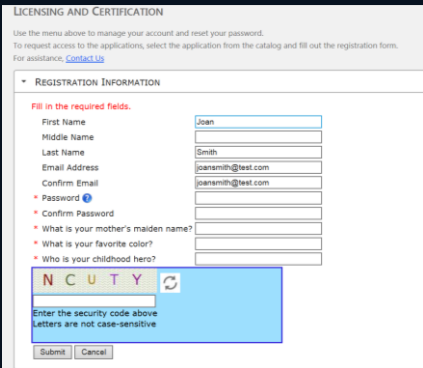
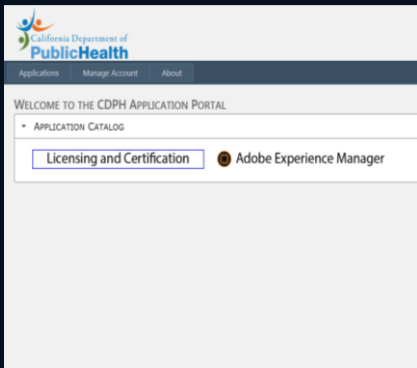
Annual License Application

- Online Application System
 - Manufactured Cannabis Licensing System (MCLS)
 - Launches mid-December 2017
 - Access through MCSB website
 - Submit your application, update your information, make a payment
- Resources and Guides Coming Soon



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CDPH Application Portal



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Manufactured Cannabis Licensing System (MCLS)

MANUFACTURED CANNABIS LICENSING SYSTEM (MCLS) Update Profile

Welcome to Manufactured Cannabis Licensing System, **Joan**

 We still need some information about you.
[Click here](#) to complete your profile

My Profile

[Change Password](#)

[My Documents](#)

Tools

[FAQs](#)

[Helpful Hints](#)

[Contact Us](#)



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Individual Profile

- All Owners must complete an Individual Profile
- Live Scan
 - Criminal Disclosure

Individual Profile Number – Keep this number

 MANUFACTURED CANNABIS LICENSING SYSTEM (MCLS)

Update Individual (351275) Save Other actions ▾

1 — 2 — 3 — 4

Personal Information Live Scan Disclosures Attestation and Signature



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Business Information

- Information about the Business
- Contact Information
- Other Licenses (Voluntary Survey)



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Business Information

- Add Owners to Your Business Profile
– Use Individual Profile Number

Click 'Add' to associate other owners with your business

First Name	Last Name	Title	Authorized User	Actions
Joan	Smith		Yes	Edit

Add

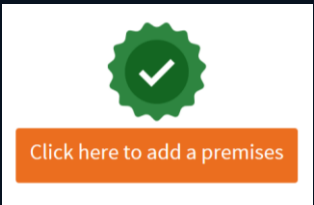
- List Financial Interest Holders



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Premises Information

- What is a Premises?
 - Where cannabis manufacturing will occur
- Physical Address
- Priority Review
- Operations
 - Gross Annual Revenue
 - Manufacturing Activities
 - Local Authorization



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License Information

Documents:

- Local Authorization
- Property Owner Authorization
- Diagram of the Premises
- Closed-Loop System Certification
- Surety Bond
- List of Cannabis Products

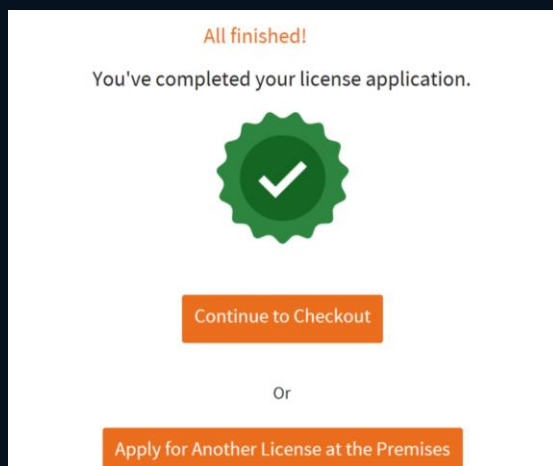
Descriptions or SOPs:

- Waste Disposal
- Inventory Control
- Quality Control
- Transportation
- Security



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Annual License Application



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Application & Licensing Fees

Application Fee – Paid when application is submitted

License Fee – Paid when application is approved

- Seven scaled tiers
- Based on gross annual revenue of the licensed premises



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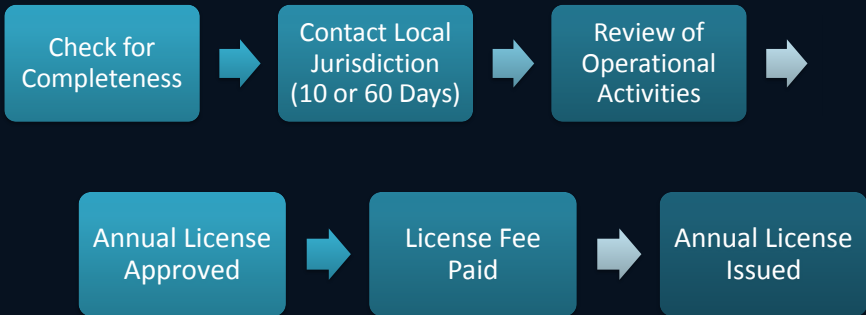
Making a Payment

- Include [Payment Instructions Form](#)
- Payment Forms Accepted
 - Application Fee: Cashier’s Check, Money Order or Credit Card
 - Make Payments to “California Department of Public Health”
 - License Fee: Credit Card, E-Check, Cash
- Cash Location
 - Sacramento (Opening Soon)



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How We Process Annual Applications



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ANNUAL LICENSE

AFTER YOU RECEIVE YOUR LICENSE



Next Steps

- After you apply for your annual license:
 - Sign Up for Track-and-Trace Webinar
- Tracking Movement of Cannabis Products
 - Temporary License – Sales Invoice
 - Annual License – Track-and-Trace
- Compliance Through Education



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Transition Period (Jan 1 – July 1, 2018)

License Designations:

- A- and M-License overlap (until July 1, 2018)

Existing manufactured products:

- Secondary packaging: Child-resistant
- Add: Government warning statement, amount of THC/CBD per serving and per package

All products manufactured on/after January 1, 2018
must meet THC limits and product restrictions



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Resources

Manufactured Cannabis Safety Branch (MCSB)

www.cdph.ca.gov/mcsb

mcsb@cdph.ca.gov

Cannabis Portal

www.cannabis.ca.gov

Cannabizfile

www.sos.ca.gov

California Department of Tax & Fee Administration (CDTFA)

www.cdtfa.ca.gov

www.cdtfa.gov/industry/cannabis.html



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Thank You

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www.cdph.ca.gov/mcsb
mcsb@cdph.ca.gov

Cannabis Portal
www.cannabis.ca.gov

