NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
DPH-17-010 Cannabis Manufacturing Licensing
Notice Published: July 13, 2018

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulation permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS
The Department is conducting a 45-day written comment period during which time any interested person or such person’s duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

PUBLIC HEARING
The Department has scheduled public hearings to accept comments on the proposed action. Any person may present statements or arguments described in the Informative Digest. The Department requests, but does not require, that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

Dates, Times and Locations:
1. **July 30, 2018, 10:00 am**, 900 E. Birch Street, Valencia Room, Brea, CA 92821
2. **August 20, 2018, 10:00 am**, 901 Myrtle Avenue, Eureka, CA 95501
3. **August 27, 2018, 10:00 am**, 8400 Edes Avenue, Oakland, CA 94621

An agenda for the public hearing will be posted at the time and place of hearing location.

WRITTEN COMMENT PERIOD
Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on August 27, 2018, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.
Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier “DPH-17-010 Cannabis Manufacturing Licensing” in the subject line to facilitate timely identification and review of the comment;

2. By fax transmission to: (916) 636-6220;

3. By United States Postal Service to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814; or


All submitted comments should include the regulation package identifier, “DPH-17-010 Cannabis Manufacturing Licensing,” author’s name and mailing address.

AUTHORITY AND REFERENCE
The Department is proposing to adopt the proposed rulemaking under the authority provided in sections 26001, 26011.5, 26012, 26013, 26050.1, 26051.5, 26054.2, 26057, 26106, 26120, and 26130 of the Business and Professions Code.

The Department is proposing to add Chapter 13 to Division 1 of Title 17, California Code of Regulations in order to implement, interpret, or make specific sections 26000, 26001, 26010, 26011.5, 26012, 26013, 26030, 26031, 26050, 26050.1, 26051.5, 26053, 26054.2, 26055, 26057, 26058, 26060, 26062.5, 26067, 26070, 26106, 26120, 26121, 26130, 26131, 26132, 26133, 26134, 26135, 26140, 26150, 26160, 26161, 26180 of the Business and Professions Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW
These proposed regulations will implement the Department’s responsibilities under the Medicinal and Adult-Use Cannabis Regulation and Safety Act (Act).

The proposed regulations will:

1. Establish the licensing scheme, including temporary licenses, for manufacturers of cannabis products, including the requirements for applications and the individuals or entities that are required to submit applications;
2. Establish licensing fees;
3. Set minimum standards for extraction processes;
4. Set minimum standards for sanitary manufacturing practices;
5. Establish licensee responsibilities for operations, including, among others, requirements related to security, training, recordkeeping, and disposal;
6. Establish quality and safety standards for finished manufactured cannabis products; and
7. Establish packaging and labeling standards for manufactured cannabis products.

BACKGROUND
The Department is one of several state agencies with regulatory authority under the Act. Primary responsibilities for administration and enforcement of the Act are divided between:

- **California Department of Food and Agriculture** (CDFA), which will license and regulate cannabis cultivators and oversee the state track-and-trace system.

- **Bureau of Cannabis Control** (Bureau) in the Department of Consumer Affairs, which will license and regulate retailers, distributors, testing labs, and microbusinesses.

- **California Department of Public Health** (The Department), which will license and regulate cannabis product manufacturers. The Department is also required to develop standards for the production and labeling of all adult-use and medical cannabis products.

The Department worked closely with the Bureau and CDFA during the regulation development process to ensure consistency, when appropriate.

*Legislative History of Cannabis Regulation*
In 1996, voters approved the Compassionate Use Act (CUA), which allowed patients and primary caregivers to obtain and use medical marijuana as recommended by a physician, and prohibits physicians from being punished or denied any right or privilege for making a medical marijuana recommendation to a patient. In 2003, Chapter 875, Statutes of 2003 (Senate Bill (SB) 420) established the Medical Marijuana Program (MMP), which allowed patients and primary caregivers to collectively and cooperatively cultivate medical marijuana. It also established a medical marijuana card program for patients to use on a voluntary basis.

Passed in 2015, Assembly Bill (AB) 266 established the Medical Marijuana Regulation and Safety Act (MMRSA) for the statewide licensure and regulation of medical marijuana. The primary portion of MMRSA was contained in the California Business and Professions Code sections 19300-19360. Also passed in 2015, AB 243 and SB 643, in
conjunction with AB 266, established the regulatory framework to regulate the
cultivation, sale, testing, manufacturing and transportation of medical cannabis in
California. In 2016, several provisions of the MMRSA were amended through SB 837,
including a renaming of the law to the Medical Cannabis Regulation and Safety Act
(MCRSA).

Prior to the enactment of the MMRSA, California had no regulatory oversight of
cannabis at the state level. Some local jurisdictions regulated cannabis cultivation or
dispensaries.

In November 2016, voters passed Proposition 64, the Adult Use of Marijuana Act
(AUMA). AUMA legalized the use of marijuana in California for non-medical purposes
for adults aged 21 and over. AUMA was codified in separate code sections from the
MCRSA. In June 2017, the Governor signed SB 94 (Committee on Budget and Fiscal
Review, Chapter 27, Statutes of 2017), a budget trailer bill to combine AUMA and
MCRSA into a single, unified law known as the Medicinal and Adult-Use Cannabis
Regulation and Safety Act (Act).

**History of Regulatory Proposal**
The Department initially released a rulemaking package in April 2017 (published April
28, 2017, in the Regulatory Notice Register) under the authority provided in MCRSA.
Upon repeal of the MCRSA, the Department withdrew its rulemaking package.
However, the package had already been through a 45-day public comment period and
hundreds of public comments were submitted. The Department reviewed and
considered all comments and made revisions to the text, as appropriate. The revised
text, which also incorporated rules and requirements for adult-use cannabis, was
released as emergency regulations in November 2017 and became effective December
7, 2017.

Previous to the adoption of emergency regulations, the Department of Consumer Affairs
formed the state’s Cannabis Advisory Committee under the Bureau of Cannabis
Control. The Committee was formed under authority from Business and Professions
Code Section 26014. The Committee’s members were announced on October 4, 2017,
and meetings began on November 16, 2017. The Committee has met six times since
the adoption of the emergency regulations and has made a series of recommendations
to the agencies responsible for cannabis licensing. These recommendations come from
subject-specific subcommittees, which include subcommittees on Enforcement,
Microbusiness, Public Health and Youth, Retailers, Testing Laboratories, Cultivators,
Distributors, Equity, Licensing Application, and Manufacturers.
**Establishment of Permanent Regulations**

This proposed rulemaking action will make the emergency regulations permanent. Some revisions to the emergency text have been made as a result of public comments received, as well as clarifications needed in response to questions received by the Department.

The Act, in Business and Professions Code (BPC) §26011.5, establishes protection of the public as the primary concern. The Department developed this regulatory proposal with that in mind by establishing the following:

- Safety requirements for extraction processes, especially volatile solvent extractions, to minimize potential negative effects;
- Security requirements to protect the physical safety of employees and to minimize the potential for diversion of cannabis or cannabis products;
- Standard operating procedures to protect the integrity of the cannabis product throughout the manufacturing process by preventing contamination; and
- Requirements to ensure uniform distribution of cannabinoids.

**Policy Statement Overview**

*Problem Statement:*
The Department is required to license manufacturers of cannabis products, to set manufacturing standards for cannabis products, and to set packaging and labeling standards for such products.

*Objectives (Goals):*
The objective of these proposed regulations is to implement the Department’s responsibility under the Act to protect public health and safety through the licensing of cannabis product manufacturers, the establishment of safety standards for cannabis products, and the establishment of minimum standards for packaging and labeling of cannabis products.

*Benefits:*
By providing regulatory oversight to a previously unregulated industry, there are numerous benefits to the health and welfare of California residents, worker safety, and the state’s environment. These include:

- consumer awareness and protections by establishing packaging and labeling requirements and setting product standards
- worker safety by setting minimum operational and labor requirements
- manufacturing and safety measures designed to protect workers and the public from accidents involving extractions
STATEMENTS OF DETERMINATIONS AND ECONOMIC ANALYSIS
In addition to the following determinations, the Department has prepared a Standardized Regulatory Impact Analysis (SRIA), which is required for major regulations by the Administrative Procedure Act. Due to its extensive length and in the interests of ease-of-reading for the regulated public, the SRIA has been included as a separate document in this regulatory package.

EVALUATION AS TO WHETHER THE REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS
The Department has made a determination that these regulations are not inconsistent or incompatible with existing state regulations. As the oversight of cannabis commercial activity is a newly-created state responsibility, no other state regulations are already in existence that address the same topic.

DOCUMENTS INCORPORATED BY REFERENCE
The incorporation by reference of requirements published by the United States Food and Drug Administration, the United States Department of Agriculture, and the United States Consumer Product Safety Commission in Sections 40252, 40270, 40272, 40306, and 40415 is appropriate as publishing these documents in the California Code of Regulations would be cumbersome, impractical, and unnecessary. The documents consist of numerous pages of text. The documents are easily available to the public, and will be made available on the Department’s website, and can be provided to anyone upon request to the Department.

The incorporation by reference in Section 40126 of Form CDPH 9041 (11/17) is appropriate for ease of use to the regulated industry. The form is designed so that individuals can complete it electronically, then mail or email it to the Department. It is unnecessary to duplicate the information in the text of the regulation itself, as adopting the form by reference will provide clarity and ease of use.

The following documents are incorporated by reference in the proposed regulation text:

1. Form CDPH 9041 (11/17)


https://www.fda.gov/RegulatoryInformation/Guidances/ucm056174.htm#CHPTA


**NONDUPLICATION**

These proposed regulations include many of the statutory provisions imposed by the Act. Such provisions are duplicated in these proposed regulations in order to provide clarity and ease of understanding to the reader, and to provide a single location in which members of the public and the regulated industry can find applicable requirements. These proposed regulations should not be considered duplicative of federal law, even in instances where federal law has been incorporated by reference. Due to the nature of cannabis products, specifically that they are considered by statute neither a food nor a drug, existing federal rules are not applicable to cannabis products. Specific inclusion of the federal rules in the Department’s regulations is necessary for the Department to hold cannabis product manufacturers responsible for the same health and safety precautions as manufacturers of food and drug products.

**MANDATED BY FEDERAL LAW OR REGULATIONS**
The Department has made a determination that this proposal is not mandated by federal law or regulations.

**LOCAL MANDATE**
The Department has determined that this regulatory action would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

**FISCAL IMPACT ASSESSMENT**
A. Cost to Any Local Agency or School District: None.
B. **Cost or Savings to Any State Agency:** Funding for the Department for FY 2017-18 is $13.5 million appropriated from the Cannabis Control Fund.

C. **Other Nondiscretionary Cost or Savings Imposed on Local Agencies:** None.

D. **Cost or Savings in Federal Funding to the State:** None.

**HOUSING COSTS**
The Department has determined that this proposed action will not have an impact on housing costs.

**SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE**
The Department has determined that the proposed regulatory action would have a significant economic impact on California business enterprises and individuals that has a statewide is over $50 million.

The following businesses will be affected:
- Manufacturers of cannabis extracts.
- Manufacturers of cannabis products.

The projected reporting, record keeping, and other compliance requirements that would result from the proposed action include:

1. The following records are required to be kept:
   - The acquisition of cannabis, including raw cannabis or cannabis extract;
   - The disposition of all acquired cannabis;
   - Employee training activities;
   - Equipment calibration and maintenance; and
   - Operational activities.

2. The following compliance requirements will be imposed:
   - Licensees must develop standard operating procedures and adhere to minimum standards related to sanitary manufacturing practices;
   - Licensees must establish minimum security requirements;
   - Licensees must establish inventory control procedures;
   - Licensees must adhere to specified packaging and labeling requirements.

3. There are no specific reporting requirements beyond the recordkeeping requirements.
The Department has considered proposed alternatives that would lessen any adverse economic impact on business and invites you to submit proposals. Submissions may include the following considerations:

(i) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to businesses.

(ii) Consolidation or simplification of compliance and reporting requirements for businesses.


(iv) Exemption or partial exemption from the regulatory requirements for businesses.

STATEMENT OF RESULTS OF THE STANDARDIZED REGULATORY IMPACT ANALYSIS (SRIA)

The Department has determined that the regulations affect the following as described:

A. The creation or elimination of jobs within the State of California. The proposal will positively impact the creation of jobs in California. See the SRIA for further details.

B. The creation of new businesses or the elimination of existing businesses within the State of California. The proposal will impact the creation of new businesses or result in the elimination of existing businesses within California. See the SRIA for further details.

C. The competitive advantages or disadvantages of businesses currently doing business within the State of California. The proposal will impact the competitive advantages or disadvantages of businesses currently doing business in California. See the SRIA for further details.

D. The increase or decrease of investment in the state. The proposal will impact the level of investment in the state. See the SRIA for further details.

E. The incentive for innovation in products, materials, and processes. The proposal will impact the incentive for innovation. See the SRIA for further details.

F. The benefits of the regulations including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, and the state’s environment or quality of life. This proposal will benefit public health and safety of California residents and worker safety. See the SRIA for further details.
SUMMARY OF DEPARTMENT OF FINANCE REVIEW OF SRIA AND DEPARTMENT RESPONSE

Department of Finance Comment #1: "Manufacturers have choices about where to locate their business, and to the extent that they concentrate in jurisdictions where local permitting is cheaper, the regulatory costs will be lower. However, if this leads to more concentrated production, the demand for transportation of goods would likely be higher in these areas."

Department Response: We agree with this statement. State taxes and fees on manufacturers are applied uniformly across the state and no distinction is made based on where the business is located. Once a manufacturer decides to operate, state taxes and fees are expected to have a minimal, if any, effect on the decision of where the manufacturer will locate. Local taxes and fees will be relevant to where businesses choose to establish themselves as well as proximity to suppliers, customers and other cannabis businesses.

The Humboldt Institute for Interdisciplinary Marijuana Research (HIIMR), an economic team based at California State University, Humboldt, and contracted by the Department to conduct research and economic analyses for this regulatory package, estimates that for manufacturers, more than one third of the total Department regulatory costs on manufacturers is due to the local component while less than two thirds is due to the state component. Local costs would total $49.6 million or 6.4 percent of manufacturer sales in the long run. To arrive at this, HIIMR assumed a “typical” level based on local cannabis manufacturer taxes and fees, excluding very high jurisdictions. The ease with which a business is capable of moving to another local jurisdiction will affect a business’s ability to avoid high local fees. For manufacturers in particular, the incentive to locate in low-cost areas is strong because transportation costs are low relative to product value. The cannabis oil used to make concentrates, edibles, and topicals is light in weight, and the resulting products are typically highly valued relative to their weight. Additionally, if a manufacturer wanted to relocate to a low cost area, the moving costs are fairly modest and can be spread over a number of years. All of these factors suggest that manufacturers’ location choices are highly responsive to city and county taxes and fees. Local jurisdictions that charge relatively high fees and taxes can expect to attract and retain relatively few manufacturers and receive little revenue. There has been anecdotal evidence that the revenue from cannabis fees turned out to be lower than expected in some localities.

The landscape continues to change at the local level. But a reasonable range of cost differences between jurisdictions can be assumed in order to demonstrate the importance of local fees. Suppose that a “low fee” jurisdiction has local annual fees
equal to $1,000 and taxes at 2 percent and that a “high fee” jurisdiction has local annual fees equal to $5,000 and taxes at 10 percent. Simulations indicate that if all localities were “low fee” then total industry local costs would be 2.2 percent of manufacturer sales, while if all localities were “high fee” then total industry local costs would be 11 percent. This is a fairly large difference of almost nine percentage points in costs, which would have an impact on profits and likely cause firms to move to “low fee” jurisdictions. It is beyond the scope of the SRIA to calculate the revenue maximizing fee and tax rates, but cities are likely to find that lowering fees and tax rates attracts manufacturers, increases overall revenue, and generates additional transportation service.

**DOF Comment #2**: “The SRIA may be understating the amount of business creation and destruction by assuming many existing, unlicensed manufacturers become licensed. If instead they shut down and new businesses emerge, there would be more turnover.”

**Department Response**: HIIMR has assumed that in the near future, manufacturers that seek a license (particularly for the adult-use segment) come mostly from the currently unlicensed California market. But it is certainly possible that many unlicensed manufacturers remain unlicensed or shut down, and this may be true especially for smaller-sized manufacturers. If this is the case, then adult-use manufacturers will largely be newly created firms. In the long run, the expectation is for a normal firm “turnover” of 10 percent of existing firms.

**DOF Comment #3**: “It is possible that input prices may fall more than the SRIA assumes. While this would hurt cultivator profits, it may help manufacturers and lead to greater expansion in the sector than estimated.”

**Department Response**: There is uncertainty as to the magnitude of input price changes, but it is certainly possible that cannabis flower and trim prices will fall greater than expected. As anticipated, the price of processed cannabis has continued to fall since the SRIA was submitted. In the last couple of years in California, and in states that have legalized adult-use cannabis, manufactured cannabis sales rise as a percent of cannabis sales. It is expected that this will continue into the future. HIIMR’s analysis indicates that it will be easier for cannabis manufacturers to maintain stronger profit margins, given a greater ability to differentiate their products and exercise some market pricing power, as compared to those who sell flower cannabis products. In turn, if input prices are lower than expected and profits margins are large, it is expected that additional entry into the manufactured market is possible.
**New regulatory feature**

Subsequent to the completion of the SRIA, the licensing authorities have revised the requirements regarding “A” and “M” licenses. Cannabis businesses will only submit a single license application, rather than an application for each market. Upon licensure, businesses will be able to conduct commercial activities with all other licensees.

In HIIMR’s modeling, this does not change the number of firms estimated to seek licensing. However, manufacturers who previously would have obtained two licenses will now obtain only one license. These manufacturers will also report higher sales, because sales will be the combination of adult-use and medical products. The impact on total license fees paid by the manufacturer is uncertain and depends on the distribution of firms by size and the number of new entrants, as existing medical licensees entering the adult-use market no longer need a separate license. The higher combined sales may push the manufacturer into a higher revenue tier with a higher license fee but the impact on total license fees paid depends on sales. For example, a manufacturer with $750,000 in adult-use sales and $750,000 in medical sales pays $15,000 for each license, for a total of $30,000. If the manufacturer need only purchase one combined license with sales of $1,500,000, the license fee is $25,000. On the other hand, a manufacturer with $75,000 in adult-use sales and $75,000 in medical sales pays $2,000 for each license, for a total of $4,000. If the manufacturer need only purchase one combined license with sales of $150,000, the license fee is $7,500.

This regulatory change will therefore have an ambiguous effect on total licensing costs for manufacturers that will be driven by the distribution of manufacturers in each license tier. The shape of this distribution will become more clear within the first year or two of licensing.

**COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS**

The cost impacts that a representative person or business would necessarily incur in reasonable compliance with the proposed action and that are known to the Department are estimated to be about $50,000. See the attached SRIA for further details.

**BUSINESS REPORTING REQUIREMENT**

In order to protect public health and safety, the regulations establish minimum requirements for record keeping by cannabis product manufacturers. Business and Professions Code section 26160 requires licensees to keep accurate records of commercial cannabis activity, and Business and Professions Code section 26067 requires the use of a track-and-trace program to track the movement of cannabis items through the distribution chain. It is necessary for the health, safety, or welfare of the people of the state that the regulation apply to businesses.
EFFECT ON SMALL BUSINESS
The Department has determined that the proposed regulatory action may affect small businesses.

CONSIDERATION OF ALTERNATIVES
The Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed regulatory action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Several elements of the proposed rulemaking package have alternatives that were considered by the Department prior to the commencement of this rulemaking:

1. Background investigations for all employees. The Department considered requiring that all persons employed by a manufacturing operation undergo a Live Scan criminal history check, as owners are required to do. This alternative was rejected as too costly for both the industry and the Department, with no corresponding increase in public health protection.

2. Product imprints. The Department considered mandating that a warning symbol be imprinted directly on edible products. Many infused products don’t have a surface that is conducive to printing, stamping, or marking. The Department found no evidence that product imprints reduce exposure by minors.

3. Mandatory identification badges for cannabis industry employees. The Department decided not to mandate the use of identification badges. Identification badges can pose a risk of contamination in the manufacturing process. Other provisions of the regulation require jewelry and other items to be secured or removed so that they cannot dangle or fall into ingredients or products. Mandating the issuance of identification badges would run contrary to this provision. Nothing would prohibit a licensee from issuing identification badges if the licensee determines the use of such badges does not pose a risk of contamination and is appropriate to ensure the security of the premises.

CONTACT PERSON
Inquiries regarding the proposed regulatory action can be directed to Linda M. Cortez, with the Office of Regulations at (916) 440-7807, or the designated backup contact, Dawn Basicano at (916) 440-7367.
AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS
The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 558-1710 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT
The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

FINAL STATEMENT OF REASONS
A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS
Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov and by clicking on the following: Programs, Office of Regulations, and the Proposed Regulations link.