State of California—Health and Human Services Agency
California Department of Public Health

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NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
DPH-17-004 Medical Cannabis Manufacturing
Notice Published: April 28, 2017

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

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. June 8, 2017, 10:00 am, 50 D Street, Room 410A/410B, Santa Rosa, CA 95404
2. June 13, 2017, 10:00 am, 1350 Front Street, Auditorium, San Diego, CA 92101

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 June 13, 2017, 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-17-004 Medical Cannabis Manufacturing"** in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission to: (916) 440-5747;
3. By United States Postal Service to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814; or
4. Hand-delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier, **"DPH-17-004 Medical Cannabis Manufacturing,"** author's name and mailing address.

AUTHORITY AND REFERENCE

The Department is proposing to adopt the proposed rulemaking under the authority provided in sections 19302.1, 19303, 19304, 19307, 19323, 19341 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 19300.5, 19300.7 19302.1, 19303, 19304, 19307, 19308, 19316, 19320, 19321, 19323,19324, 19327, 19335, 19341, 19344, 19347.2, 19347.5, 19347.6, 19347.7, 19347.8, and 19350 of the Business and Professions Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

These proposed regulations will implement the Department's responsibilities under the Medical Cannabis Regulation and Safety Act (Act).
The proposed regulations will:

1. Establish the licensing scheme for manufacturers of medical 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 create, issue, and suspend or revoke licenses for the *cultivation* of medical cannabis.
- **Bureau of Medical Cannabis Regulation** (Bureau) in the Department of Consumer Affairs, which will administer, enforce, create, issue, renew, discipline, suspend, and/or revoke licenses for the transportation, storage unrelated to

manufacturing activities, and sale of medical marijuana within the state. The Bureau will issue licenses to *distributors*, *transporters*, *testing laboratories,* and *dispensaries*.

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

Legislative History of Cannabis Regulation:
In 1996, voters approved the Compassionate Use Act (CUA), which allows 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 allows 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 licensure and regulation of medical marijuana. 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 Act. Prior to the enactment of the Act, California had no regulatory oversight of medical 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). The AUMA legalized the use of marijuana in California for non-medical purposes for adults aged 21 and over. The provisions of the AUMA are similar to those of the Act, but not identical. Additionally, the two laws are contained in different divisions of the Business and Professions Code. Consequently, the Department will be developing separate regulatory packages to implement the two separate laws. This package implements the requirements for medical cannabis oversight as mandated by the Act.

The Act establishes protection of the public as the primary concern of regulatory agencies[1]. The Department considers public health and safety a critical element of protecting the public and developed this proposal to protect public health and safety through the establishment of 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;
- Standard operating procedures to protect the integrity of the product throughout

[1] Business and Professions Code section 19303.

the manufacturing process by preventing contamination; and
- Requirements to ensure uniform distribution of cannabinoids.

Policy Statement Overview

Problem Statement: Recently enacted statute requires the Department to license manufacturers of medical 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.

These proposed regulations serve to implement the Department's responsibilities under the Act.

Benefits: The benefits of the regulations, including benefits to the health and welfare of California residents, worker safety, and the state's environment, are as follows:

- The proposal increases and strengthens the health and welfare of California residents, and worker safety by providing regulatory oversight to a previously unregulated industry. The proposed regulations improve health benefits through packaging and labeling requirements, minimum facility requirements, and product standards. As a result of these regulations, the Department anticipates a cleaner and safer product that results in fewer instances of over-consumption, consumption by children, potential exposure to product contaminants, or other related harm to the consumer.
- These proposed regulations will also positively impact public safety through safety measures designed to reduce accidents involving explosions and fires.

STATEMENTS OF DETERMINATIONS AND ECONOMIC IMPACT ASSESSMENT

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 an attachment to the Initial Statement of Reasons.

EVALUATION AS TO WHETER 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 medical cannabis commercial activity is a newly-created state responsibility, no other state regulations are already in existence that address the same topic.

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 2016-17 is $3.5 million appropriated from the Marijuana Control Fund.
C. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.
D. Cost or Savings in Federal Funding to the State: None.

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 statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This regulation is considered a Major Regulation with a statewide impact of over $50 million.

The following businesses will be affected:

- Manufacturers of cannabis extracts
- Manufacturers of cannabis products

There are record keeping and other compliance requirements that would result from the proposed action.

This proposal requires the following records to be kept:

a. The acquisition of cannabis, including raw cannabis or cannabis extract;
b. The disposition of all acquired cannabis;
c. Employee training activities;
d. Equipment calibration and maintenance; and
e. Operational activities.

And the following compliance requirements will be imposed:

a. Licensees must develop standard operating procedures and adhere to minimum standards related to sanitary manufacturing practices;
b. Licenses must establish minimum security requirements;
c. Licensees must establish inventory control procedures;
d. Licensees must adhere to specified packaging and labeling requirements.

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.
(iii) The use of performance standards rather than prescriptive standards.
(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 REPONSE

Comment #1: The SRIA must include an estimate of the local revenue and expenditure increases from the state regulating medical cannabis.

Department Response: The SRIA has been revised to include this information. Local permitting is not under the Department's control, but we assume that some localities will develop a permitting system for cannabis manufacturers and implement enforcement of local regulations. Local permitting by cities and counties may turn out to be significant and we estimated local permitting to be the second largest cost of regulation to cannabis manufacturers, behind the Department's license fees. Local permitting will necessitate more staff time for application review, record keeping, and inspection, among other tasks. There will also be extra costs associated with these tasks. However, local governments are authorized to charge a fee to cover associated costs and the extra local workload and costs are expected to be funded by fee revenue. We estimate

new local revenue to be $4.65 million if half of the manufacturers pay $9,000 in cannabis-specific local permit fees and half pay $300 in general business permits fees.

Comment #2: The impacts of the manufacturer regulations should be compared with both the current economic situation (without recreational use), and with the future situation that allows for recreational use. The IMPLAN calculations all show increases in investment, jobs, and GDP for the state as a result of medical cannabis regulations when compared with only the recreational cannabis being available, but investment and jobs in the medical cannabis sector will actually shrink compared with the current situation where both medical and recreational cannabis are unregulated. Both aspects are important to discuss for the impacts to be understood by the reader.

Department Response: The SRIA has been revised to include this information. Table 6 in the SRIA (page 32) shows how we expect manufactured cannabis markets to look in 2019 compared to our model baseline at the start of 2018 (the model baseline continues the assumptions of the 2016 medical market and also assumes that one-half of the illegal market moves to the recreational market). In the 2019 medical manufactured cannabis market, retail sales revenue is 34.3 percent lower than currently in 2016. That means we expect manufactured medical cannabis retail sales revenue to fall by $224 million from $651 million to $427 million. This is a very large decline in medical manufacturer sales, but the decline will be offset by gains to the recreational market as consumers shift. The direct effect of the reduced medical manufactured production is a loss of 1,418 workers, of which there are many part-time and seasonal workers, especially in extraction. Businesses that produce goods for medical cannabis manufacturers see a decrease of 406 workers, and workers and proprietors earn less income and their lower spending supports 285 fewer workers. The total effect is 2,110 fewer workers hired in the medical cannabis industry in California, compared to the current 2016 situation, solely due to lower demand for manufactured medical cannabis. The decreased demand for medical cannabis also leads to a decrease in spending of $78 million at the factory, with an indirect impact of $83 million less spending compared to current baseline. It must be emphasized, however, that this analysis examines only the impact to the medical market and does not take into account any potential gains from an expanded adult use market. These impacts are expected to be offset by an increase in spending associated with the recreational use market.

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 19327 requires licensees to keep accurate records of commercial cannabis activity, and Business and Professions Code section 19335 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 regulations apply to businesses.

EFFECT ON SMALL BUSINESS

The Department has determined that the proposed regulatory action may affect small businesses.

CONSIDERATION OF REASONABLE 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.

Several elements of the proposed rulemaking package have alternatives that were considered and ultimately rejected.

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 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 has decided not to mandate the use of identification badges at this time. Identification badges can pose a risk of contamination in the manufacturing process. Other provisions of the regulations 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 Basciano 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 (or at http://archive.cdph.ca.gov after May 1, 2017) by clicking on these links, in the following order: Decisions Pending & Opportunities for Public Participation, Proposed Regulations.