



KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

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



EDMUND G. BROWN JR.
Governor

FINDING OF EMERGENCY
Emergency Cannabis Regulations for
Cannabis Manufacturing Licensing
DPH-17-010E

The director of the California Department of Public Health (Department) finds that an emergency exists and that the proposed emergency regulations, as required by the legislature, are necessary to address a situation that calls for immediate action to avoid serious harm to the public peace, health, safety or general welfare.

NOTICE AND INTRODUCTION

Notice is hereby given that the California Department of Public Health proposes to adopt the regulations described below. Government Code section 11346.1(a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6.

DEEMED EMERGENCY

The Department has been provided specific statutory authority to adopt emergency regulations as needed to implement the Medicinal and Adult Use Cannabis Regulation and Safety Act (Act), codified in Business and Professions Code section 26000 et seq. Section 26013, subdivision (b), paragraph (3) of the Business and Professions Code states that “the initial adoption of emergency regulations and readoption of emergency regulations authorized by this section shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare.”

The Department previously published a proposed regulatory action in April 2017, to implement the Medical Cannabis Regulation and Safety Act (MCRSA). In July 2017, the MCRSA was repealed, leaving the Department without statutory authority to proceed with its previous rulemaking package. The same bill that repealed the MCRSA also incorporated provisions from Proposition 64, or the Adult Use of Marijuana Act,



approved by the voters in November 2016. Proposition 64 required that the Department, along with the other state cannabis licensing authorities, begin issuing licenses on January 1, 2018. After the two laws were combined in July, the licensing authorities did not have sufficient time to promulgate permanent regulations to meet their statutory responsibility to begin issuing licenses as of January 1, 2018.

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 480 et seq, 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; section 37104 of the Food and Agriculture Code; and section 11018.1 of the Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Purpose

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 manufactured 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 cannabis.
- **Bureau of Cannabis Control (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 cannabis within the state. The Bureau will issue licenses to distributors, 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 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 MCRSA. Prior to the enactment of the MCRSA, 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 cannabis in California for non-medical purposes for adults aged 21 and over. Thereafter, SB 94 (Chapter 27, Statutes of 2017)

made changes to the Medical Cannabis Regulation and Safety Act (MCRSA) and the Adult Use of Marijuana Act (AUMA). It combined portions of both laws to create the Medicinal and Adult-Use Cannabis Regulation and Safety Act (Act).

The Act establishes protection of the public as the primary concern of regulatory agencies¹. 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 the manufacturing process by preventing contamination; and
- Product standards to protect public health by minimizing unintentional consumption by children and adults.

Policy Statement Overview

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

The emergency regulations proposed generally include the following overall areas to implement the Act:

- Provides descriptions of the types of licenses to be issued by the Department;
- Establishes required information to be submitted by an applicant for a license;
- Provides processes for the rejection of license applications;
- Establishes procedures for temporary licenses and priority licensing;

¹ Business and Professions Code section 26011.5.

- Provides food and product safety processes in manufacturing and labeling;
- Provides safety and security practices, and Cannabis waste disposal practices;
- Establishes limitations of ingredients of Cannabis products including potency;
- Provides requirements regarding child proof packaging, and other packaging requirements.

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 more sanitary 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

The Department has determined that the proposed regulatory action would have a significant economic impact on California business enterprises and individuals. The permanent regulations package will be accompanied by a Standardized Regulatory Impact Assessment (SRIA) that will address the economic impact of the regulations.

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.

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 \$12.8 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.

DOCUMENTS RELIED UPON

The following studies, reports, and laws were used by the Department in development of these regulations:

- A. Dunkelberger, *The Statutory Basis for the FDA's Food Safety Assurance Programs: From GMP, to Emergency Permit Control, to HACCP* (1995) 50 Food & Drug L.J. 357.
- B. Colorado Department of Revenue, Marijuana Enforcement Division. House Bill 14-1366 Marijuana Edibles Work Group Report. (January 30, 2015).
- C. Guohua, et al., "Drug use and fatal motor vehicle crashes: A case-control study." (2013) 60 Accident Analysis and Prevention, pages 205-210.
- D. Janczyk et al., "Two Hundred and Thirteen Cases of Marijuana Toxicoses in Dogs." (2014) 46 Veterinary Human Toxicology, pages 19-21.
- E. Mead et al., *Food Related Illness and Death in the United States* (Sept.-Oct. 1999) 5 Journal of Emerging Infectious Diseases, pages 607-625.
- F. Meier, A review of the additive health risk of cannabis and tobacco co-use (Sept. 1, 2016) 166 Drug Alcohol Depend., pages 6-12.
- G. National Academies of Sciences, Engineering, and Medicine, The, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (2017). The National Academies Press.
- H. Pava-Ripoll et al., *Detection of Foodborne Bacterial Pathogens from Individual Filth Flies* (Feb. 13, 2015) Journal of Visualized Experiments.
- I. United States Department of Justice, Memorandum ("Cole Memo"), (Aug. 29, 2013).
- J. United States Food and Drug Administration (USFDA), 2014 Reportable Food Registry (2014).
- K. USFDA, Bad Bug Book, The, Foodborne Pathogenic Microorganisms and Natural Toxins (2012).
- L. USFDA, Compliance Policy Guidance: Filth from Insects, Rodents, and other Pests in Foods (Last updated: Nov. 14, 2002).
- M. USFDA, 21 C.F.R. Part 117. *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*.

- N. USFDA, 21 C.F.R. Part 111. *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.*
- O. USFDA Compliance Policy Guide. Foods, Adulteration Involving Hard or Sharp Foreign Objects (Last Updated: May 2005).
- P. World Health Organization (WHO), Hazard prevention and control in the work environment: Airborne dust (August 1999).
- Q. WHO, Cockroaches: Their biology, distribution and control (1999).

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.