

FINAL STATEMENT OF REASONS

DPH-17-010 Cannabis Manufacturing Licensing

I. HISTORY OF PROPOSED ACTION

This proposed rulemaking package was originally contained in two emergency regulatory proposals – DPH-17-010E (File # 2017-1127-04E, originally adopted in December 2017 and File # 2018-0525-02E, readopted in June 2018) and DPH-17-013E (File # 2018-0403-03E, originally adopted in April 2018 and File # 2018-1001-02EE, readopted in October 2018).

The Notice of Proposed Rulemaking for this regulatory proposal was published on July 13, 2018, which began the 45-day public comment period. The Notice of Proposed Rulemaking, the proposed text, the Initial Statement of Reasons, and the Standard Regulatory Impact Assessment were distributed to individuals who requested to be placed on the Department of Public Health's (Department) rulemaking notification list, as well as individuals who requested to be on the notification list for updates issued from the Manufactured Cannabis Safety Branch (MCSB). The above referenced documents were also made available on the Department's internet website.

During the 45-day public comment period, which closed August 27, 2018, the Department received 432 submitted comments from organizations and individuals. The Department also held three public hearings, in which a total of 30 individuals provided oral comments. These comments are summarized and responded to in *Attachment A: 45-day Public Comments*.

On October 19, 2018, the Department released changes to the proposed text and documents added to the rulemaking file for a 15-day public review period. The Notice of Public Availability of Proposed Changes, modified text, a Supplement to the Initial Statement of Reasons, and Modified Text Explanation of Changes were distributed to individuals who requested to be placed on the Department's rulemaking notification list, as well as individuals who had submitted a comment during the 45-day comment period.

The 15-day public comment period closed November 5, 2018. These comments are summarized and responded to in *Attachment B: 15-Day Public Comments*.

II. UPDATE OF INITIAL STATEMENT OF REASONS

In addition to the Initial Statement of Reasons, the Department made available for public review a Supplement to the Statement of Reasons and a Modified Text Explanation of Changes. Those three documents are incorporated by reference into this document.

The Department also provides the following additional information related to the modified text made available during 15-Day Comment Period #1:

Section 40100(k) added “homogeneity” to the definition of “cannabis product quality.” Multi-serving cannabis products are required to be homogeneous, which is defined in further regulatory provisions as meaning that each serving contains the same concentration of THC, within the variance established by the Bureau of Cannabis Control. The addition of the term to the definition of cannabis product quality is necessary so that licensees understand that processes and procedures should be developed with the end goal of homogeneity of the cannabis product, rather than just the end goal of free from contaminants.

Section 40100(dd)(2)(B) was added to clarify that the preparation of pre-rolls is not a manufacturing activity. This provision is necessary to conform to the Bureau of Cannabis Control’s draft regulations that allow the preparation of pre-rolls by a distributor and so that the regulated industry understands what activities can be conducted without holding a manufacturing license.

Section 40100(dd)(2)(E) was added to clarify that adding cannabinoid content to the label on the package of cannabis or cannabis products by the distributor is not a manufacturing activity. This addition is necessary to align with Section 40409, which has been added to allow distributors to label the cannabinoid content based on the Certificate of Analysis after the product has been tested. Currently, all cannabis products must be packaged and labeled by a manufacturer prior to testing. This provision is necessary so that the regulated industry understands what activities can be conducted without holding a manufacturing license.

Section 40128(b)(5) was added to align with Assembly Bill (AB) 2799 (Chapter 971, Statutes of 2018) related to OSHA training requirements. AB 2799 was signed by the Governor to require licensees to attest that they employ, or will employ within one year of licensure, an individual who has completed a specified Cal/OSHA training course. This provision has been added to the text because it is needed to align the regulations with the revised statute. Although the statutory provision will not become effective until January 1, 2019, the Department anticipates that this regulation will become effective after that date.

Section 40129(a)(7) is amended to add foreign limited liability companies to the list of business structures to be disclosed on the application, and makes a clarifying change to refer to the proper form issued by the Secretary of State. During the period of the emergency regulations, numerous questions came to the Department as to whether this section, which referred only to foreign corporations, also was applicable to foreign limited liability companies. In order for applicants to understand the requirements, it was necessary for the Department to clarify that if a business is registered in another state (i.e. a “foreign” business), the Secretary of State registration form must be submitted.

Sections 40129(a)(8) and (9) are amended to make a grammatical change.

Section 40129(a)(12) is amended to include additional examples of business formation documents to add further clarity on the types of documents that can be submitted.

Section 40130 (a)(9) is added to require an owner to disclose ownership or financial interest in any other cannabis business licensed under the Medicinal and Adult Use Cannabis Regulation and Safety Act (Act). This requirement conforms to requirements of the other licensing agencies and is necessary in order for the Department to determine that the owner does not hold ownership interest in a licensed testing lab, which is prohibited under Business and Professions Code §26053.

Section 40179 is added to specify what happens to a license in the event of an owner's death, incapacity, receivership, assignment for the benefit of creditors of a licensee, or other event rendering an owner incapable of performing the duties associated with the license. This section is necessary as it provides an owner's successor in interest the opportunity to transition the owner's operations and/or wind-down the licensed business' affairs prior to expiration of the license while ensuring the Department is aware of the situation and that licensing rules are being followed. Although the successor in interest may continue operations on the licensed business premises for a period of time, the successor in interest is not automatically guaranteed issuance of a state cannabis license. Requiring the successor in interest to submit a new application for licensure after a certain period enables the Department to determine a new owner's fitness for licensure as required by the Act. The requirements of this section duplicate requirements established by the Bureau of Cannabis Control.

Specifically, this section adds the following requirements:

Subsection (a) requires that in the event of an owner's death, incapacity, receivership, assignment for the benefit of creditors of a licensee, or other event rendering an owner incapable of performing the duties associated with the license, the owner(s) successor in interest shall notify the Department within 10 days. The Department determined that 10 days was a reasonable amount of time as it is consistent with the requirement for a licensee to notify the Department of an owner change and allows sufficient time to keep Department records up-to-date for consistent compliance and enforcement.

Subsection (b) requires the successor in interest to submit their name, the name of the owner(s) being succeeded, the license number, phone number, mailing address, and email address of the owner(s) being succeeded and the successor in interest and documentation the owner(s) is incapable of performing the duties relative to the applicable license. This information is necessary in order to confirm that the owner is incapable of performing duties and to provide the relevant contact information for the successor in interest.

Subsection (c) allows the Department to give the successor in interest approval to continue to operate on the premises for a specified period of time. This provision is necessary so that the successor in interest is aware of the timeframe in which they will be permitted to operate the business.

Subsection (d) specifies the successor in interest is subject to all terms and conditions under which a state cannabis license is held pursuant to the Act. This section is necessary to clarify that even though the successor in interest does not yet hold a cannabis license, they must follow the same requirements.

Subsection (e) specifies that the approval by the Department to continue to operate does not create a vested right to the issuance of a state cannabis license. The Department has a statutory obligation to determine each individual owner's fitness for licensure. Approval to operate as a successor in interest in order to address business needs does not automatically mean that the individual is qualified to hold a cannabis license.

Section 40205(e) is amended to remove the requirement that monitoring equipment be stored in secure rooms or access-controlled environments. Monitoring equipment such as video screens are commonly located in areas of a building that are not access-controlled. There is no regulatory purpose to this requirement, so it has been removed.

Section 40277(c) is amended based on comments received by CalCannabis from the California Agricultural Commissioners and Sealers Association to clarify that a weighmaster certificate is not required when the cannabis or cannabis product is weighed for entry into the track-and-trace system. This provision is necessary to clarify for licensees that the more onerous requirement of issuing a weighmaster certificate is required only when the weighed product is sent to another licensee, not when weighed for entry into track-and-trace.

Section 40550(b) is amended to clarify that the Department may inspect any area of a premises where manufacturing activities are occurring. This provision is necessary to conform to the Department's authority to oversee manufacturing activities.

Section 40550(g) and (h) are added to clarify the Department's authority to collect evidence and make copies of materials for purposes of investigations and enforcement proceedings. This provision is necessary so that the licensee can expect what actions the Department may take during an investigation.

Section 40551(c) is modified to change calendar days to business days to better correspond to current Department practice. This provision is necessary to clarify to licensees the time period in which they can expect to receive the information from the Department.

LOCAL MANDATE DETERMINATION

MAUCRSA developed a dual licensing system. State licensing authorities must ensure that local cities and counties authorize a licensee to operate. MCSB contacts local jurisdictions upon receipt of an annual license to ensure licensees are in compliance with local laws and regulations. The Department has determined that the regulation 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, nor are there any other nondiscretionary costs imposed. Local jurisdictions have various mechanisms through which they recoup their costs of issuing and overseeing cannabis businesses including but not limited to building permits, business licenses, and taxes.

ALTERNATIVES CONSIDERED

The Department has determined that no reasonable alternative considered by the Department, or that have otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the regulation action is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. This determination is based, in part, upon the standardized regulatory impact analysis of the proposed regulation and, in part, upon the statement of benefits identified in the Informative Digest contained in the Notice of Proposed Rulemaking.

IMPACT ON BUSINESSES

The Department has determined that the regulations would not have a significant adverse statewide economic impact based on the findings of the Standardized Regulatory Impact Assessment. The Department did receive comments from applicants and licensees on the high cost of conducting business due to state and local taxes and licensing fees. The Department does not have any data at the current time to analyze the impact of these costs since cannabis regulations are in the first year of implementation. Per the statute, the Department must cover its regulatory and licensing program costs through licensing fees.

IMPACT ON OTHER STATE AGENCIES

With the implementation of cannabis regulations statewide, CDPH anticipates there will be costs to other state agencies that oversee and regulate similar industries. These departments may recoup their costs either through existing mechanisms (fees, permits, taxes, etc.) or may request funding through a Budget Change Proposal. CDPH did not receive any cost estimates from other state agencies related to cannabis workload.

However, other state agency workload may be affected by the growth in the regulated cannabis distribution, testing and retailing activities that is facilitated by these regulations. This could include agencies dealing with labor regulations.

FISCAL IMPACT ASSESMENT

As described in the Notice of Proposed Regulatory Action, the Department's objective with these regulations is to implement the Department's responsibilities under the Act to protect public health and safety. This is done through the licensing of cannabis product manufacturers, the establishment of safety standards for cannabis products and the establishment of standards for packaging and labeling of cannabis products. Through the public comment process, the Department has received feedback and incorporated any feedback that improves the Department's ability to meet its mandated regulatory objectives.

The Department finds at this time it does not need to change the Manufactured Cannabis Safety Branch's program goals, licensing fees, or budget. The program's budget authority to implement manufacturing regulations in Fiscal Year 2018-19 is \$26,590,000.