

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



# 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.

The Department has found that the deemed emergency circumstances that necessitated the original emergency regulatory package in December 2017 still exist and that the readoption of the regulations are necessary to protect the public health, safety, and 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 (OAL), 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 has found that the deemed emergency circumstances that necessitated the original emergency regulatory package adopted by OAL on December 7, 2017, still exist and that the readoption of the regulations are necessary to protect the public peace, health, safety, and general welfare.

Significant progress is being made toward permanent adoption of the regulations. The Department has been receiving feedback from the public and has been revising regulatory requirements to address any elements that are unclear or otherwise in need of revision. This work has been performed in conjunction with the CalCannabis Cultivation Licensing (CalCannabis) within the Department of Food and Agriculture, and the Bureau of Cannabis Control (Bureau) within the Department of Consumer Affairs. Such coordination between separate agencies can lengthen the time needed to finalize regulatory provisions.

Secondly, and most critically, the Department has been receiving feedback on the emergency regulations from the Cannabis Advisory Committee (CAC), a statutorily-created task force with specific authority to advise the licensing agencies on the regulations. The CAC is subject to the Bagley-Keene Open Meetings Act, and consequently, all meetings of the CAC and its subcommittees are publically noticed and open to the public and public comment. At the meeting on January 18, 2018, the CAC created subcommittees to discuss and advise on regulatory topics. The subcommittees met on February 15, 2018, and March 1, 2018, and developed recommendations to present to the full CAC for adoption. The full CAC met March 15, 2018, but due to the length of the agenda and the number of recommendations for discussion, the CAC did not finish reviewing all of the recommendations. The remaining recommendations, including those from the manufacturing subcommittee, were held over to the next scheduled meeting, held May 17, 2018.

The Department was reluctant to finalize and release the proposed permanent regulations prior to receipt of the remaining CAC recommendations. However, whenever possible, recommendations raised by the CAC thus far have been considered in the revisions of the regulations for readoption. Further revisions resulting from CAC recommendations will be forthcoming in the regulations for permanent adoption.

#### **AUTHORITY AND REFERENCE**

The Department is proposing to adopt the proposed rulemaking under the authority provided in sections 26012, 26013, 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 26001, 26010, 26011.5, 26012, 26013, 26030, 26031, 26050, 26050.1, 26051.5, 26053, 26054, 26054.2, 26055, 26057, 26058, 26060, 26062.5, 26067, 26070, 26105, 26106, 26120, 26121, 26130, 26131, 26132, 26133, 26134, 26135, 26140, 26150, 26154, 26160, 26161, 26180 of the Business and Professions Code; and section 11018.1 of the Health and Safety Code.

#### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

The purpose and objective, background of existing laws, policy statement overview, problem statement, and benefits of these regulations, are incorporated by reference, along with all other documents, from the previous approved rulemaking file, under file number 2017-1127-04E.

The Department has reviewed and revised the proposed emergency regulations in response to recommendations from the CAC, and comments and questions received from the public. The changes to be made are as follows:

#### License Designations – "A" and "M" Licenses

In the readoption of the emergency regulations, the Department, along with the Bureau and CalCannabis, is proposing to modify the restrictions on adult-use ("A") and medicinal ("M") licenses. The Act provides that licenses must be issued with "a clear designation indicating whether the license is for commercial adult-use cannabis activity as distinct from commercial medical cannabis activity by prominently affixing an "A" or "M," respectively" (BPC Section 26050(b)). Based on this requirement, the licensing agencies made a policy determination that the A and M markets were to be kept separate, requiring licensed premises that conducted both activities to have two licenses and to conduct activities only with other licensees of the same designation. When the emergency regulations were adopted, the licensing agencies allowed for a transition period in which licensees could conduct business with any other license holder, regardless of the A or M designation on the license until July 1, 2018. Since the release of the emergency regulations, the licensing agencies have received significant feedback to allow licensees to continue to conduct business across market streams regardless of the A and M designation.

#### **History of the Separate Adult-Use and Medicinal Licenses**

Initially, the licensing authorities determined that during a transitional period from January 1, 2018 through June 30, 2018 it was necessary to allow A and M designated licensees to conduct business with each other irrespective of the designation because the adult-use market was new and there would be no place to obtain cannabis goods (cannabis and cannabis products) except from the existing medicinal market. Following

the transitional period, the licensing authorities had prescribed the requirement that A designated licensees could only do business with other A designated licensees and M designated licensees could only do business with other M designated licensees. For instance, a cultivator with an M license could only sell to a rmanufacturer who also possessed an M license.

Since noticing the emergency regulations, the licensing authorities have had feedback from licensees, potential licensees, and the Cannabis Advisory Committee that the transition period should be extended, or the provision allowing licensees to do business with other licensees regardless of the A or M designation should be made permanent. Licensees have expressed concerns that if the supply chains are separate for A and M either supply chain could end up with a shortage or an excess of cannabis goods. In either scenario, licensees and customers may be encouraged to turn to the illicit market to either divert excess cannabis goods or to purchase cannabis goods.

The number of licensed cannabis businesses is still relatively low when compared to the number of businesses in operation before January 1, 2018. The reasons for this are varied, but a substantial aspect is the lack of locally-available licenses. Only about one-third of local jurisdictions have permitted cannabis businesses within the jurisdiction, and many of those are limited to medicinal cannabis activity only<sup>1</sup>. A lack of other licensees with which to conduct business can prove difficult for licensed businesses. For instance, a licensed manufacturer whose long-standing sources of plant material are unlicensed must find a new source of plant material and potentially cease operations until a new supply is procured. Similarly, if the number of potential retailers to which to distribute products has suddenly dropped by two-thirds due to lack of a local license, licensed manufacturers are left with an excess of products. Although the Department anticipates that the market chain will eventually even out, in the meantime, this difficulty in acquiring and providing cannabis and cannabis products can discourage other businesses from entering the legal market. Fewer businesses entering the legal market exacerbates the market chain issues, which further discourages businesses.

The unregulated cannabis market, which has thrived in California for over 20 years, poses a significant threat to the success of the legal cannabis marketplace. Further, the unregulated market poses a threat to public health and safety. Unlicensed businesses are less likely to follow protocols established to protect public health, including restrictions on pesticide use and good manufacturing practices. Cannabis and cannabis products in the unregulated market will not be tested to ensure the product is free of contaminants or contains the stated amount of THC (tetrahydrocannabinol, the psychoactive element in cannabis). Because of the potential threat to public health and

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<sup>&</sup>lt;sup>1</sup> Staggs and Wheeler, *Marijuana Laws for Every City and County? Our Database Shows California Slow to Accept Prop. 64*, The Orange County Register (April 9, 2018), <a href="https://www.ocregister.com/2018/04/09/database-of-marijuana-rules-from-every-city-and-county-in-california-shows-slow-acceptance-of-prop-64/">https://www.ocregister.com/2018/04/09/database-of-marijuana-rules-from-every-city-and-county-in-california-shows-slow-acceptance-of-prop-64/</a>

safety, it is a matter of statewide concern to ensure the unregulated cannabis market begins to diminish and the legal cannabis market can grow.

CDPH is not aware of any public health or safety threat that has been created during the transition period as a result of allowing commercial cannabis activity between market designations. The only difference between cannabis products for adult-use and cannabis products for medicinal use is a regulatory requirement that limits adult-use products to 1,000 mg THC per package for products that are not edibles; and caps non-edible medicinal-use products at 2,000 mg THC. There is no difference for edible products. All other aspects of the manufacturing process are identical, such as requirements for good manufacturing practices, safety procedures, and informative labeling, and licensees are permitted to operate under both an A and an M license at the same premises. Cannabis and cannabis products will still be tracked "from seed to sale" through the track-and-trace system. Consequently, the Department sees no threat to public health and safety by removing the regulatory restrictions regarding medicinal and adult-use cannabis, cannabis products, and commercial activity.

#### **Basis for the Modified Regulations**

Based on feedback from stakeholders and the Cannabis Advisory Committee, the licensing authorities have further reviewed the MAUCRSA and have determined that it should be implemented in a manner that allows licensees to buy or sell cannabis or cannabis products to each other irrespective of their A or M designation. Business and Professions Code section 26053 states that all commercial cannabis activity shall be conducted between licensees. However, nothing in the MAUCRSA expressly states that A designated licensees may only do business with other A designated licensees or that M designated licensees may only do business with other M designated licensees. Further, Business and Professions Code section 26013 which provides direction to licensing authorities and states that regulations shall not "make compliance so onerous that the operation under a cannabis license is not worthy of being carried out in practice by a reasonably prudent businessperson." The licensing authorities have determined that there is a high likelihood that requiring the A and M supply chains to remain separate will perpetuate, rather than reduce and eliminate, the illicit market for cannabis. Licensees that are unable to acquire cannabis goods or sell their cannabis goods because of under saturation or over saturation of cannabis goods within their supply chain would be placed in a position where the requirement of complying with a separate supply chain for A and M designated cannabis goods is so onerous that continuing to operate under their cannabis license is not worthy of being carried out in practice by them.

Amending the current regulation to allow for licensing authorities to issue licenses with an A and M, and allowing licensees to conduct business with other licensees regardless of the A and M designation is necessary to avoid increased costs due to the duplication of applications and allows licensees the ability to procure and sell product based on the

commercial cannabis market's demands. This amendment is consistent with Business and Professions Code section 26050, subdivision (b), which requires licensing authorities to affix and A or M on each license. Nothing in that section prohibits licensing authorities from affixing both designations, and indeed it expressly provides that, with limited exceptions stated in statute, "the requirements for A-licenses and M-licenses shall be the same." The licensing authorities have discretion to permit the applicants to fill out one application, pay one license fee, and obtain one license rather than insisting on the formality of two licenses, particularly when there are virtually no distinctions between A and M licenses identified by statute. Where MAUCURSA or local ordinances require such a distinction to be made, the Department will require an M or A designation, as appropriate.

To that end, the Department, in conjunction with CalCannabis and the Bureau, is proposing to eliminate any regulatory restriction on commercial activities between license designations. Commercial cannabis licenses will still include a designation of "M" or "A," but will also allow businesses to select both "M" and "A" activity to be covered by a single license. Licensees will then be able to conduct commercial cannabis activity with any other licensed business, regardless of the designation on the license. In this way, the Department hopes to increase participation in the legal cannabis market, simplify the application process, and facilitate commercial cannabis activity between licensees. This will ease the regulatory burden on the industry and provide stronger public health and safety protections.

#### Specific Text Amendments Related to A and M Designations

Originally, unrestricted commercial cannabis activities between licensees, regardless of the "M" or "A" designation, was to exist only in the transition period. However, based on feedback from the regulated public, in particular during the CAC process, the Department, the Bureau and CalCannabis have made the policy decision to eliminate any such restrictions beyond the transition period. This change is reflected in the Department's proposed re-adoption, and will also be included in the Department's permanent rulemaking package. Therefore, the restrictions in the Department's regulations for one to select either "M" or "A" have been eliminated, allowing licenses to select "M" or "A" or both. The specific changes to the regulatory text to accommodate this policy change are as follows:

- Subsection (e) is amended to conform the definition of "adult-use market" with other changes related to A and M designations.
- Subsection (kk)(2)(C) has been added to clarify that adding a sticker stating "FOR MEDICAL USE ONLY" to a cannabis product at a retail premises does not constitute a manufacturing activity (and therefore can be done without a

manufacturing license). Most labeling activity is considered to be a manufacturing activity. However, the manufacturer will not be aware of which type of consumer the cannabis product will be sold to – medicinal or adult-use – and therefore cannot be reasonably expected to label the product. If a retailer sells a cannabis product to a medicinal user, it poses no threat to public health to allow the retailer to sticker the product accordingly.

#### Section 40115

• Subsections (c) and (d) are deleted in order to allow M licensees and A licensees to conduct business with each other.

#### Section 40118

 Subsection (a) is deleted to allow a license to be issued for activity in both the medicinal and adult-use markets. The remaining subsections are renumbered; these changes are explained later in this document.

#### Section 40126

Grammatical edits to authority section.

#### Section 40129

 Subsection (a)(11) is amended to allow a license to be issued for activity in both the medicinal and adult-use markets.

#### Section 40131

- Subsection (b) is amended to allow a license to be issued for activity in both the medicinal and adult-use markets.
- Subsection (h) is amended to clarify that the gross annual revenue to be reported to the Department is that from all cannabis products manufactured at the licensed premises, and does not need to be split by market.

#### Section 40133

Grammatical edits to authority section

#### Section 40175

 Subsections (c) and (d) are deleted in order to allow M licensees and A licensees to conduct business with each other.

#### Section 40306

 Subsections (a) and (b) are amended to provide more clarity as to the THC limitations on products.

#### Section 40408

 Subsection (a)(4) is amended to clarify that products that the manufacturer intends to be sold only in the medicinal market can be labeled as "FOR MEDICAL USE ONLY," and to require products over 1,000 mg THC (which can only be sold to a medicinal customer) to be labeled as "FOR MEDICAL USE ONLY."

#### Section 40600

 This section is eliminated to allow M licenses and A licenses to conduct business regardless of the A and M designation.

#### Other Technical, Clarifying Changes

The text for readoption contains other necessary technical and clarifying edits, as follows:

#### Section 40100

- Subsection (f) conforms reference to "Business and Professions Code" to "Act."
- Subsection (n) technical, grammatical edits.
- Subsection (z) adds the definition of "harvest batch." This is a statutory definition and has been added to the regulation for ease of use by the public.
- Current subsections (z) (yy) are renumbered.
- Subsection (kk)(2)(D) revisions have been made to conform to CalCannabis regulations.
- Subsection (kk)(2)(E) clarifies that the processing of nonmanufactured cannabis products ("pre-rolls") in accordance with CalCannabis regulations is not a manufacturing activity that requires a license from the Department. This is a technical change needed to conform Department and CalCannabis regulations.
- Subsection (II) technical edits to clarify the definition of "manufacturing."
- Subsection (uu) conforms reference of the Business and Professions Code to "Act."
- Subsection (yy) technical edits to clarify the definition of "product identity."

#### Section 40101

• Subsection (b) - technical amendments to conform regulatory provisions to statutory provisions.

- Subsection (a) technical, grammatical edits.
- Prior subsection (e) is renumbered to subsection (c).

• Subsetion (a) – technical edits.

#### Section 40118

- Subsection (b) is renumbered to subsection (a) (existing subsection (a) is deleted).
- Subsection (a)(1) technical, grammatical edits to add a citation to the appropriate definition.
- Subsection (a)(1)(D) technical edits to conform this section to other Department regulations regarding shared-use facilities.
- Subsection (a)(2) technical, grammatical edits to add a citation to the appropriate definition.
- Subsections (a)(2)(A), (B), and (C) technical edits to conform this section to other Department regulations regarding shared-use facilities.
- Subsections (a)(3)(A) and (B) technical edits to conform this section to other Department regulations regarding shared-use facilities.
- Subsection (a)(4) technical, clarifying edits to delete duplicative information.
- Subsection (a)(5) technical edits to conform this section to other Department regulations regarding shared-use facilities.

#### Section 40128

- Subsection (a)(2) technical, clarifying edits.
- Subsection (a)(3) technical amendment to add citation reference to a later section that was added in the Department's emergency regulation package regarding CEQA compliance and shared-use facilities. The addition is necessary for clarity to the regulated public.
- Subsection (a)(4) technical amendment to add citation reference to later sections.
- Subsection (b)(2) amended to conform regulatory provisions to the Department's online licensing system, which does not require a notarized statement.

- Subsection (a)(2) amended to conform regulatory provisions to the Department's online licensing system.
- Subsection (a)(3) technical, clarifying edits.
- Subsection (a)(7) technical, clarifying edits to conform with the California Corporations Code.
- Subsection (a)(9) technical, clarifying edits.

- Subsection (a)(9)(A) amended to conform regulatory provisions to the Department's online licensing system.
- Subsection (a)(9)(B) amended to conform regulatory provisions to the Department's online licensing system.
- Subsection (a)(10) technical edits to clarify bond requirements.
- Subsection (b) technical, clarifying edits.

- Subsection (a) technical edits to remove an unnecessary definition.
- Subsection (a)(3) technical, clarifying edits.
- Subsection (a)(7) technical, clarifying edits.
- Subsection (b) technical edit.

#### Section 40131

- Subsection (d) amended to conform regulatory provisions to the Department's online licensing system, which includes a product list.
- Subsection (e) technical edit to include "email address" as a method of contact.
- Subsection (f) technical edit to include "email address," and to clarify that the inclusion of an additional contact person is not mandatory.
- Subsection (j)(3) clarifying edits to better describe to the regulated industry the information that the Department expects to be submitted with the application.
- Subsection (j)(5) technical, grammatical edits.
- Subsection (I) technical amendment to conform to further regulatory provisions and the Department's online licensing system, both of which require a copy of the closed loop certification to be submitted as part of the application.
- Previous subsection (I) has been renumbered to subsection (m).

#### Section 40150

- Subsection (a) Paragraph (1) has been added to specify that applicants for license types 7, 6, N, and P are subject to the \$1,000 processing fee.
- Subsection (a)(2) added to conform this section to the \$500 application fee for Type S licenses established by the Department's emergency regulation DPH-17-013E. This provision is necessary to clarify which license applications are subject to which application fee, and that not all application fees are \$1,000.

#### Section 40155

 Subsection (a) – technical edits to clarify that the Department will notify an applicant of license approval via email or through the Department's online licensing system. • Subsection (c) - technical edits to clarify that the license fee must be paid in full before the license becomes effective.

#### Section 40165

- Subsection (a)(4) technical edits to conform references to "Business and Professions Code" to "Act."
- Subsection (a)(5) technical edits.
- Subsection (a)(6) technical edits to conform regulatory provisions to the Act and the Penal Code.

#### Section 40169

• Subsections (a) and (b) – technical edits to internally conform the subsections and ensure the same terminology is used throughout the subsections.

#### Section 40175

 Subsection (b) - technical edits to clarify that the restriction against employing individuals under 21 years of age also applies to retaining individuals under age 21. MAUCRSA's intent is to ensure that individuals under age 21 are not exposed to cannabis or cannabis products. This revised provision is in keeping with the intent of the law.

#### Section 40177

- Subsection (a) technical, clarifying edits.
- Subsection (a)(2) clarifying edits to account for the application fee for Type S license established by DPH-17-013E.
- Subsection (d) technical, clarifying edits.

#### Section 40178

Clarifying, technical edits.

- Subsection (c) clarifying edits.
- Previous subsection (d) is incorporated into subsection (c) to provide clarifying edits.
- Previous subsection (e) is renumbered as subsection (d) and makes clarification edits regarding submittal of forms for renewal applications.
- Previous subsection (g) is renumbered as (e).

- Previous subsection (f) is deleted to conform regulatory provisions to the requirements of the Department's online licensing system.
- Subsection (f) added to clarify the manner in which the Department will notify an applicant of the renewal application approval or denial.

- The introduction has been updated to clarify that licensees are required to develop and implement a security plan.
- Subsection (a) technical edits to clarify that a licensee must prevent access to the manufacturing premises by all unauthorized persons, not only unauthorized personnel.

#### Section 40205

- Subsection (f) technical edits. The intent of the provision is to limit access to surveillance equipment by placing the equipment in secure rooms. As written, the provision appears to require that cameras be located only in secure rooms. This edit will clarify that the storage device is required to be kept secure.
- Subsection (g) technical and clarifying edits. Type S licensees may not be directly keeping surveillance recordings on their own recording device. This requirement has been amended to clarify that the licensee is required to ensure that the recordings are kept, rather than requiring them to be kept on the licensee's own device.

#### Section 40220

• Subsection (a)(4) – technical edit to add a citation to the applicable regulatory section.

#### Section 40225

 Subsection (a) – edits to clarify that the certification for the closed loop system deems that it is safe to use with the intended solvent.

#### Section 40232

- Subsection (b)(1) technical, grammatical edits.
- Subsection (b)(4) technical, grammatical edits.
- Subsection (b)(5) technical, grammatical edits.
- Subsection (b)(6) technical, grammatical edits.
- Subsection (b)(7) technical, grammatical edits.
- Subsection (b)(8) technical, grammatical edits.

- Subsection (a) technical, clarifying edits.
- Subsection (e) technical, clarifying edit to use a defined term ("premises"), rather than an undefined one ("facility").

• Title and introduction - technical, clarifying edit to use a defined term ("premises"), rather than an undefined one ("facility").

#### Section 40238

- Subsection (a) technical, clarifying edit to use a defined term ("premises"), rather than an undefined one ("facility").
- Subsection (e) technical, clarifying edit to use a defined term ("premises"), rather than an undefined one ("facility").

#### Section 40240

- Introduction technical, clarifying edit to use a defined term ("premises"), rather than an undefined one ("facility").
- Subsection (d) technical edit to clarify that the licensee must ensure that employees have access to toilet facilities, not that each premises is required to have separate toilet facilities, and a technical, clarifying edit to use a defined term ("premises"), rather than an undefined one ("facility").
- Subsection (e) technical, clarifying edit to use a defined term ("premises"), rather than an undefined one ("facility").

#### Section 40242

• Subsection (f) – technical edit to remove an improper reference.

#### Section 40250

Subsection (c) - grammatical edits.

#### Section 40252

- Subsection (b) grammatical edits to correct a misspelling.
- Subsection (e) technical edit. As currently written, the provision appears to require raw materials and other ingredients to be held in bulk. The edit is necessary to clarify the intent of the provision, which is to require that raw materials and other ingredients must be held in containers that protect against contamination.

• Introduction is updated with a minor clarifying edit to specify that the hazards to be prevented are those to the consumer, and to use a defined term ("premises"), rather than an undefined one ("facility").

#### Section 40258

Subsection (b) – grammatical edit.

#### Section 40260

- Subsection (a)(1) grammatical edit.
- Subsection (a)(2) grammatical edit.
- Subsection (a)(3) grammatical edit.
- Subsection (b)(1) grammatical edit.
- Subsection (b)(2) grammatical edit.

#### Section 40262

Subsection (b)(1) – technical amendment to clarify that the master manufacturing
protocol must include the intended cannabinoid content of the product to be
manufactured, not the intended cannabinoid content per serving. Without this
clarifying edit, manufacturers of products that are not sold with "servings" will not
understand the requirement.

#### Section 40264

• Subsection (b)(4) – technical and clarifying edits to conform to statutory provisions that cannabis can only be obtained from a licensee.

#### Section 40266

• Subsection (d)(6) – grammatical edit.

#### Section 40268

- Subsection (d)(2) technical and clarifying edits.
- Subsection (d)(3) subsection removed as it is duplicative of other regulatory provisions.
- Subsection (d)(4) subsection removed as it is duplicative of other regulatory provisions.

#### Section 40272

Grammatical edits to authority section

#### Section 40270

 Subsection (a) has been amended to better clarify the regulatory requirements to the regulated public. Further provisions of the Department regulations (Section 40300) refer to both juice and beverages as prohibited unless processed in

- accordance with this section. This edit is necessary to conform regulatory provisions and provide clarity.
- Subsection (b) is amended to more clearly identify the sections of the Code of Federal Regulations to which a manufacturer must adhere. Currently, the requirement is to adhere to all of subpart B, which in the context of cannabis product manufacturing, is overly broad. Some sections of subpart B establish requirements for the manufacturer to conduct specified testing before distribution to retail. Cannabis products are already required to be tested. No further public health protection is provided by requiring an additional testing step. In addition, a reference to section 120.8 of subpart A has been added. This section describes the elements to be considered in a juice hazard analysis plan. Cannabis manufacturers are already required to conduct a hazard analysis; the specific incorporation of section 120.8 simply provides manufacturers with further guidance on how to develop the hazard analysis.

 Subsection (g) – technical amendment to clarify that the provision specifically applies to cannabis waste.

#### Section 40280

- Subsection (a)(3) provision deleted and moved to new subsection (d).
- Subsection (d) added to provide a timeframe in which licensees in operation at the time the license is issued must train their existing employees. As currently written, the requirement is clear for new employees, but not for existing employees. The Department selected 90 days to conform to the existing timeline to receive food handler certification.

#### Section 40282

 Subsection (b) – amended to remove the requirement that inventory reconciliation be performed by one individual and independently verified by a second person. Very small businesses, especially Type S licensees, may be single operator businesses.

#### Section 40290

• Subsection (f) – technical and clarifying changes to remove extraneous words.

#### Section 40299

Section removed as it is no longer relevant.

- Subsection (a) technical edits to add citation to the appropriate section.
- Subsection (c) technical edits to conform regulatory provisions. Infused butter
  is allowed by statute to be manufactured as a cannabis product, but subsection
  (c) restricting refrigerated products appears to contradict the statute. The
  subsection has been amended to clarify that infused butter is allowed to be
  manufactured.
- Subsection (g) conforms reference to "Business and Professions Code" to "Act."

Subsection (e) – technical, grammatical edits.

#### Section 40306

• Subsection (b) – technical edits.

#### Section 40308

 This section is added to address a potentially significant public health concern related to cannabis and alcohol. Current regulations prohibit the sale of cannabis-infused alcoholic beverages, but exempt "tinctures" from the prohibition.

The lack of a definition of "tincture" in the Department regulations has led some manufacturers to attempt to circumvent the prohibition against cannabis-infused alcoholic beverages. The Department is aware of cannabis-infused wine offered for sale, labeled as a tincture, and sold in a standard-size wine bottle.

In order to mitigate the potential public health risk posed by cannabis-infused alcoholic beverages, the Department is proposing to limit the manner in which tinctures can be sold. The Department conducted research on tincture products currently on the market and determined that two fluid ounces was a reasonable limitation to place on the container size. The majority of tinctures available in the medicinal market appeared to meet this size limit and were also sold with a dropper. This proposal will also add the requirement to sell the product with a dropper in order for the consumer to be able to accurately assess his or her intake of cannabis.

#### Section 40400

Subsection (b) – removed as the provision is no longer relevant.

Grammatical edits to authority section

#### Section 40408

- Subsection (b) technical edit to add the proper citation.
- Subsection (c) is added for clarity. Current regulatory provisions allow the inclusion of additional information on the <u>primary</u> panel of a cannabis product. The amended provision will provide the same allowance for the <u>informational</u> panel as well.

#### Section 40410

- Introduction is amended to conform to a defined term.
- Subsection (a) grammatical edits needed to conform to statutory provisions.
- Subsection (b) grammatical edits needed to conform to statutory provisions.
- Subsection (c) grammatical edits.

#### Section 40411

Grammatical edits to authority section

#### Section 40415

• Subsection (b) – technical, grammatical edits.

#### Section 40500

- Subsection (a)(1) edited to clarify that a license must be prominently displayed.
- Subsection (b) technical edits needed for clarification. As currently written, the
  provision appeared to prohibit onsite employees from accessing outdated
  standard operating procedures at all. This was not the intent of the provision;
  rather, the provision is intended to ensure that onsite employees don't mistakenly
  use outdated procedures.

#### Section 40510

- Subsections (d)(2),(3), and (4) amended to conform to terminology used by the track-and-trace system.
- Subsection (f) amended to conform to terminology used by the track-and-trace system.

#### Section 40512

• Subsections (a) and (b)(3), (4), and (5) - amended to conform to terminology used by the track-and-trace system.

 Subsection (c) – technical amendment to add the statutory sunset date for temporary licenses.

#### Section 40517

 Subsection (b) – Technical edits to clarify that after UID tags have been received, commercial cannabis activities have to be recorded in the system, even if the 30 day window to upload existing inventory has not yet closed.

#### Section 40550

- Subsection (b) technical edits.
- Subsection (f) grammatical edits.

#### Subchapter 7

• Subsection 40601 (e) - clarifying that the transition period ends July 1, 2018.

#### 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 \$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.

#### **INCORPORATION BY REFERENCE**

This Finding of Emergency hereby incorporates by reference all documents in the previous approved rulemaking file under file number 2017-1127-04E.

#### **DOCUMENTS RELIED UPON**

In addition to the documents cited in the initial adoption of emergency regulations, the following documents have been relied upon for this proposed rulemaking:

A. Cannabis Advisory Committee Recommendations, minutes from March 15, 2018, Committee meeting, available at <u>the Bureau of Cannabis Control</u> <u>website</u>

#### **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.