

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 # 2018-0525-02EE, 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 information related to the text made available during the 45-Day Comment Period:

Section 40116(d): Other provisions of California law, including probate law, provide for individuals to be appointed as executors, administrators, or guardians of an estate. An individual acting in these roles would not necessarily have involvement in direct, control, or management of the business. This provision clarifies that if an individual who would otherwise be prohibited from holding a license due to their employment is appointed to these roles, he or she is not prohibited from exercising those responsibilities. To the extent that the individual becomes involved in the direction, control, or management, he or she would be considered an owner. The provisions of this subsection align with the Bureau's regulatory text.

Section 40130(a)(7): an applicant is required to use a Department of Justice BCIA 8016 form provided by the Department. The version provided by the Department and available on the Department's website will contain the Department's ORI number, the unique code that the DOJ needs in order to provide the results of the fingerprint criminal history report to the Department. If an applicant has submitted an application to the Bureau or CalCannabis in addition to the Department, the same form cannot be submitted for each application. If the form does not include the Department's ORI number, the Department will not receive the applicant's criminal history and will not be able to process the application.

Section 40132(b)(2): the text of this paragraph specifically states that the paragraph applies to applicants that do not submit a copy of a local license, permit, or other authorization, but the ISOR does not include this specification. The text is correct and the public had proper notice that the paragraph was limited in scope and did not apply to all applicants. In addition, the text allows the applicant to submit a reference to where the documents can be found electronically, but the ISOR did not include this provision. CEQA documents are frequently very large, potentially hundreds of pages, and it is common practice for the documents to be made available electronically. The State of California even maintains an electronic clearinghouse for CEQA documents. Because the text is correct and the requirement is within common and accepted practice, the public received proper notice of the requirement.

Section 40159(a)(3): the text of this section is not aligned with the explanation and necessity provided in the ISOR. The text states that the Department may deny a license application if the applicant or an owner has been denied a license to engage in commercial cannabis activity by a state licensing authority. The ISOR states that the Department may deny an application if the applicant or owner has been denied a license to engage in commercial cannabis activity by a state licensing authority or a local jurisdiction. The text is correct; the intent of this section is to provide notice to the applicant that a denial by another state licensing authority may be a reason for denial by the Department. Because the text is correct, the public received proper notice of the requirement.

Section 40177(c)(1): the text of this section is not aligned with the explanation and necessity provided in the ISOR. The text states that a licensee shall request approval for a change in operation by submitting any change to the information and documents required under Section 40131. The ISOR states that a licensee shall request approval by submitting the information and documents required under 40131. The text is correct. The Department will have all of the previously submitted information on file; there is no need for the licensee to resubmit all of the information, which would be an overly onerous requirement on the business. Because the text is correct, the public received proper notice of the requirement.

Section 40180: states that a license renewal application cannot be submitted more than 60 days in advance of the expiration date of the current license. This provision is necessary to ensure that the information submitted to the Department not outdated. This provision conforms to the requirements of the Bureau and CalCannabis.

Section 40196(a): the text of this section is not aligned with the explanation and necessity provided in the ISOR. The ISOR makes reference to the “liability for theft or violations”, but that language is not in the text. This is a drafting error. The ISOR refers to a prior draft of the text that the Department ultimately decided not to include in the regulation and was inadvertently left in the ISOR. Because the text is correct, the public received proper notice of the requirement.

Section 40280(c): allows a licensee to assign responsibility for the training of individual personnel to the supervisory personnel. The licensee may not be directly involved in the day-to-day operation of the manufacturing facility, or may lack the technical expertise, especially in the case of specialized extraction equipment, to properly ensure personnel are trained. It is therefore reasonable for the licensee to delegate this responsibility to supervisory personnel. However, in order to protect public health and safety, any supervisory personnel assigned responsibility for training must have the education or experience necessary to ensure production of quality cannabis products. Otherwise, such personnel may not be able to train other personnel. This section also requires the assigned supervisory personnel to attest on an annual basis that he or she has received and understands the required training program. This is necessary so that the Department can verify that supervisory personnel assigned responsibility are aware of the training program requirements.

Section 40282: this section requires the licensee to notify the Department if the audit reveals a discrepancy of more than five percent of the documented inventory. A discrepancy in inventory between what is on-hand and what can be documented in the track-and-trace system can indicate that theft or diversion has occurred. One of the main objectives of the cannabis regulatory scheme is to prevent diversion of cannabis out of the regulated market. The Department has chosen five percent as the appropriate level for notification for several reasons. First, large operations will have large amounts of inventory. If the notification level was set too high, such as 10 percent or more, the potential amount of cannabis that could have been diverted would be very

high and therefore poses a public safety risk. If the notification level was set too low, such as one percent, very small operations would be overly burdened by frequent notifications. Second, licensees will need some time to become familiar with the track-and-trace system. The system is very complex and the Department anticipates that there will be a learning curve. If the notification level was set too low, the Department would be over-burdened with notifications that are simply inputting errors. Finally, cannabis regulation is a new program over a newly-regulated industry. There is no data for the Department to rely upon to indicate a normal or reasonable amount of inventory loss. Data from other industries is only of limited use because of the unique nature of the cannabis regulatory system. Therefore, in order to provide a clear baseline for the regulatory program, the Department considered all of the above factors and decided to set the notification level at 5 percent. To the extent that further information is available in the future, the level may be revised to be higher or lower.

Section 40500: the text of this section is not aligned with the explanation and necessity provided in the ISOR. The text uses the term “reasonable times,” but the ISOR incorrectly summarized the provision as “reasonable business hours.” The statutory requirement in BPC 26160(c) states that “all inspections and examinations of records shall be conducted during standard business hours of the licensed facility or at any other reasonable time.” The regulatory text aligns with the statutory provision; therefore the public received proper notice of the requirement.

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.” This addition 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. 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. In addition, the Department would note that the text has been amended to refer to “testing standards established by the Bureau,” rather than “limits on contaminants” specified by the Bureau. This change is necessary to conform Department regulations to the terminology used by the Bureau in order to provide clarity to the public. The regulatory requirements remain the same and the change is nonsubstantive.

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 40253(c)(2): the text of this section is not aligned with the explanation and necessity provided in the ISOR. The ISOR makes reference to “unapproved additives,” but that language is not in the text. This is a drafting error in the ISOR, which refers to a prior draft of the text that the Department ultimately decided not to include in the regulation and was inadvertently left in the ISOR. Because the text is correct, the public received proper notice of the requirement.

Section 40253(g): this subsection requires the licensee to maintain the product quality plan and documentation of preventive measures, monitoring results, and corrective actions and to make the records available to the Department. This information is necessary for the Department to ensure that manufacturing operations are being conducted in the manner specified by the licensee. In addition, in cases of product adulteration, these records will help the licensee and the Department determine the potential manufacturing failure that lead to the adulteration so that it may be resolved. This subsection further specifies that the licensee may consider the product quality plan subject to trade secret protection. The product quality plan could contain proprietary information related to the product formulation or manufacturing process. This provision is necessary to protect the licensee’s trade secrets.

Section 40255: The Modified Text made some amendments to the originally-proposed text related to the Master Manufacturing Protocol, and renumbered the section. Although the justification of necessity from the ISOR is still applicable, the necessity is duplicated in this document so that the public can align the rationale and the section numbers.

The master manufacturing protocol is similar to a recipe, except that, in addition to the ingredients and process, the master manufacturing protocol specifies the controls and processes necessary to protect the quality of a product. The master protocol is critical to ensuring consistency during manufacturing processes, and must be adequately detailed to minimize any deviation that may result in a product that fails to meet the quality standards.

Subsection (a): requires each licensee establish a written master manufacturing protocol for *each unique formulation of product manufactured and for each batch size produced*. Each unique formulation of cannabis product will have its own “recipe” and required manufacturing steps. Consequently, a master protocol is required for each type of product. A master protocol is also required for each batch size produced. As each batch size may use differing amounts of raw materials and ingredients, this requirement ensures the uniformity of each

product. The master manufacturing protocol will ensure that licensees produce cannabis products that are quality cannabis products.

Subsection (b): establishes the elements that the master manufacturing protocol must include. This provision is necessary to ensure that a complete protocol is developed for each unique formulation of product manufactured and each batch size produced. Accordingly, the master manufacturing protocol must include the following elements:

Paragraph (1): the name and batch size of the cannabis product to be manufactured. This is necessary so that employees can make sure they are using the proper protocol.

Paragraph (2): a complete list of components to be used. This is necessary so that employees can ensure they are using the correct components.

Paragraph (3): the weight or measure of each component. This is necessary so that employees can ensure they are using the correct amount of each component. This paragraph also allows the master manufacturing protocol for a given product to include the ability to adjust the amount or weight of cannabinoid-containing ingredients in order to account for the variability of cannabinoid content in harvest batches.

Paragraph (4): the identity and measurement of each ingredient that will be declared on the product label. This requirement is further necessary in order to ensure that the product label is properly prepared and accurately reflects the product ingredients. Accurate labeling helps protect consumers.

Paragraph (5): the expected yield of the finished product, based upon the quantity of components or packaging to be used in the absence of any loss or error in actual production, and the maximum and minimum percentages of expected yield beyond which a deviation investigation is necessary, material review is conducted, and a decision on the disposition of the product is made. As the manufacturing process may provide opportunities for diversion of cannabis or cannabis product, the expected yield of the finished product is necessary in order to provide a mechanism by which licensees may determine if diversion has occurred. Further, deviations greater than expected can indicate a mistake in the manufacturing process, which could lead to an unexpected amount of cannabinoids in the product.

Paragraph (6): a description of packaging and a representative label, or a cross reference to where the actual label is located. This requirement is intended to provide another means of identifying the product and ensuring proper labeling.

Paragraph (7): written instructions for all of the following:

Subparagraph (A): each point, step, or stage in the manufacturing. This is necessary so that employees can correctly manufacture the product.

Subparagraph (B): written instructions for any action to mitigate an identified risk established in the product quality plan. This is necessary so that employees take necessary actions at the right point in the manufacturing process to prevent adulteration of the product.

Subsection (c) clarifies that nothing in this chapter requires disclosure of the master manufacturing protocol to any person other than the individuals conducting activities that utilize the protocol or to the Department and its inspectors and agents. This allows the licensee to consider that master manufacturing protocol subject to trade secret protection. This subsection is necessary for the protection of the regulated industry.

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(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.

Notifications: Throughout the regulatory provisions, there is specified information that licensees are required to notify the Department about as part of the Department's regulatory oversight of cannabis manufacturers. The manner of those notifications vary.

The information required to be submitted as "written" or "in writing" are the notifications for which the Department needs to have a documented paper trail from the licensee, but for which MCLS (the Department's online licensing system) does not have the capability to accept. These notifications will be accepted via postal mail, email, or fax.

Information that can be submitted via email or MCLS is specified as such because MCLS has the capability, and is the appropriate repository, for that information. One

type of notification – that of notice of remediation and request for approval of remediation plans – is required to be sent only by email. MCLS does not currently have the capability to accept the request and postal mail would be a highly inefficient method of communication between the Department and the licensee, given the amount of time that would pass.

After the close of the 15-Day Public Comment Period, nonsubstantive text changes were necessary to correct typographical errors and ensure clarity for the public. There were numerous non-substantive grammatical, punctuation, numbering, and strike-out/underline display changes made to the final version of the text. In addition, the following non-substantive changes were also made:

40100(g): the definition of “edible” was amended to remove the reference to “conventional food and beverages.” This is an undefined term and therefore does not provide the intended clarity to the public. This amendment does not change the regulatory requirement; this change is nonsubstantive.

Section 40130(a)(8)(C) and (D): these two paragraphs were amended to conform with terminology used in the Act. The regulatory requirements remain the same and the change is nonsubstantive.

Section 40162(d): the text was revised to include the specific statutory language. Due to drafting error, some of the terms related to felony convictions involving minors and controlled substances was inadvertently excluded. Statutory requirements take precedence over regulatory requirements; thus the inclusion of the additional terms does not constitute imposition of additional regulatory requirements. Because the terminology is found in Business and Professions Code section 26057, this is a nonsubstantive change.

Section 40167(c): the text of this section is not properly aligned with statute, posing a potential clarity issue. The text has been revised to conform to statutory language. This is a nonsubstantive change; statutory provisions take precedence over regulatory provisions. As the public had knowledge of and access to the statute, the public was provided proper notice as to the procedure for appeal of a Department decision.

Section 40180(e): due to drafting error, the text mistakenly referred to changes in “owner and financial interest owner information.” “Financial interest owner” is not the proper terminology; as used throughout the Act and the regulatory text, the proper term is “financial interest holder.” Because the proper terminology is used so extensively, and the incorrect term is not used in any other place, the public could reasonably determine that this was an error in drafting. The change is nonsubstantive and is necessary to provide clarity.

Section 40240(b)(3)(C): the text was amended to remove the reference to the California Plumbing Code. The requirement did not provide the public with sufficient clarity. The amendment does not modify regulatory requirements as licensees are still

required to keep sewage systems maintained and in good repair so that they do not pose a potential source of contamination.

Section 40240(b)(3)(D): the Modified Text inadvertently omitted reference to “cannabis” and “cannabis components.” The surrounding text clearly indicates that all the requirements apply to “cannabis, components, cannabis products, contact surfaces, or packaging materials.” This is a nonsubstantive change to provide further clarity to the public.

Section 40240(b)(5)(A): this subsection establishes the requirement that a licensee provide janitorial facilities that meet the requirements of California Health and Safety Code 114279(a). This code section requires that a janitorial sink with hot and cold running water be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste. This provision is necessary to protect against potential contamination that may occur if dirty mops, buckets, and other cleaning implements are dumped or cleaned in the same sink used for cleaning dishware and other items that come into direct contact with cannabis, cannabis product components, contact surfaces, or packaging materials.

Section 40243(c)(3): the Modified Text inadvertently omitted reference to “utensils.” The surrounding text clearly indicates that all the requirements apply to “equipment and utensils.” This is a nonsubstantive change to provide further clarity to the public.

Section 40253(e)(3): the term “undesirable” has been deleted. “Pathogens” are defined in Section 40230(j) as microorganisms that can cause illness or injury. Under this definition, “undesirable” is redundant, and as it is undefined, could potentially create uncertainty. It has been deleted to provide clarity to the public.

Section 40270(b): the text contained a drafting error that inadvertently omitted part of the name of the plan reference in the document incorporated by reference. Because the document itself has always been available to the public through the rulemaking process, the public received proper notice of the requirement. The text has been amended to prevent possible clarity issues.

Section 40300(d) and (e): the text was amended to clarify that the specified prohibited product types are those products that if they did not contain cannabis would be subject to specific manufacturing requirements of the United States Food and Drug Administration. The regulatory requirements are the same, so the change is nonsubstantive and has been made to provide further clarity to the public.

Section 40305(a): In 2018, the United States Food and Drug Administration changed the name of the database referenced by the Department in this section from “Everything Added to Food...” to “Substances Added to Food....” The change was inadvertently overlooked as part of the Modified Text and has been updated now to prevent potential confusion.

Section 40409(a)(1): As discussed in the ISOR, the Department has received numerous inquiries regarding listing cannabinoid in milligrams for packages containing only dried cannabis (including pre-rolls) and has determined that listing cannabinoid content as a percentage is the appropriate labeling mechanism for the reasons provided in the ISOR. The text contained a drafting error that implied that packages of dried flower or pre-rolls could be labeled in either manner.

Section 40500(a)(9): the terms “sales invoices” and “sales receipts” were deleted from this paragraph. The terms are included in paragraph (10) and are therefore redundant.

Section 40525(d): the text has been amended to make a grammatical clarification.

Section 40550(a) and (b): the text has been amended to prevent potential confusion about the schedule and content of Department inspections. The Act provides sufficient authority related to Department inspections and these provisions are not required.

DOCUMENTS INCORPORATED BY REFERENCE

The Department has made a determination that the inclusion of certain documents in the regulation text would be cumbersome, unduly expensive, or impractical, and therefore incorporation by reference of these documents is appropriate. The documents to be incorporated were provided to the public for review and have been made available as part of the rulemaking record. The ISOR and Explanation of Modified Text also provide links to where those documents may be found online.

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 on comments received during the rulemaking process,

the standardized regulatory impact analysis of the proposed regulation, and lastly alternatives that were received during the emergency rulemaking process reflected in the Initial Statement of Reasons. Discussion on potential alternatives made as suggestions during the comments periods and the reasons for rejection of those suggestions can be found in the Summary and Response to Comments (Attachments A and B of this document).

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.