

**BUREAU OF CANNABIS CONTROL
FINDING OF EMERGENCY**

MEDICINAL AND ADULT-USE CANNABIS REGULATION

The Bureau of Cannabis Control (Bureau) finds that pursuant to Section 26013(b)(3) of the Business and Professions Code, the initial adoption of emergency regulations is deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare.

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

BACKGROUND

The Medical Cannabis Regulation and Safety Act (MCRSA) was established through a series of bills passed by the California State Legislature in 2015 and 2016. (Bus. & Prof. Code, §19300 et seq.) The MCRSA established the Bureau (known in that legislation as the Bureau of Medical Cannabis Regulation) under the California Department of Consumer Affairs and created California's first framework for the licensing, regulation, and enforcement of commercial medicinal cannabis activity.

The Control, Regulate and Tax Adult Use of Marijuana Act (AUMA) was established with the passage of Proposition 64, a voter initiative, in November 2016. AUMA legalized the nonmedicinal adult use of cannabis; established California's framework for the licensing, regulation, and enforcement of commercial nonmedicinal cannabis activity; and set a date of January 1, 2018, for the Bureau to start issuing licenses.

In June 2017, the California State Legislature passed a budget trailer bill, Senate Bill 94, that integrated MCRSA with AUMA and created the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA). (Bus. & Prof. Code, §26000 et seq.) Under MAUCRSA, a single regulatory system will govern the cannabis industry (both medicinal and adult-use) in California. Under MAUCRSA, the Bureau is charged with the licensing, regulation, and enforcement of the following types of commercial cannabis businesses: distributors, retailers, microbusinesses, temporary cannabis events, and testing laboratories, MAUCRSA provides that the Bureau must begin issuing licenses on January 1, 2018.

AUTHORITY AND REFERENCE

Business and Professions Code section 26013 authorizes the Bureau to adopt these proposed regulations. The proposed regulations implement, interpret, and make specific the MAUCRSA at Business and Professions Code section 26000 et seq.

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

This rulemaking action clarifies and makes specific licensing and enforcement criteria for commercial cannabis businesses, including: distributors, retailers, microbusinesses, temporary cannabis events, and testing laboratories. These proposed regulations would inform the applicants for licensure of the applicable meaning of key statutory terms; identify the documents and supplemental information required in an application; and provide specific clarification of terms, prohibitions, or conditions for compliance with MAUCRSA for their particular license type. Chapter 1 of these proposed regulations contains general provisions that apply to all license types, entitled All Bureau Licensees. Chapter 2 applies to distributors, Chapter 3 applies to retailers, Chapter 4 applies to microbusinesses, Chapter 5 applies to cannabis events, and Chapter 6 applies to testing laboratories. Lastly, Chapter 7 contains the enforcement provisions.

Chapter 1: All Bureau Licensees

The Bureau was established to create a comprehensive and coherent regulatory framework for an established industry that has not been regulated by the State. While MAUCRSA provides guidance on the larger macro issues, much of the implementation specifics and clarification of terms were left to the Bureau. These proposed regulations would help applicants and licensees better understand: (1) the applicable meaning of key statutory and other terms related to the Bureau's licensing program; (2) what documents and information are required in an application; and (3) specific clarification of prohibitions, requirements, or conditions for compliance with MAUCRSA.

Article 1 of the proposed regulations would make clear the applicable meaning of key statutory terms and other terms used within the proposed regulations. These terms include those relevant to requirements of licensees, such as "cannabis waste," "limited-access area," "medical cannabis patient," and "retail area." Article 2 of the proposed regulations would clarify what information and documents are required to complete an application for all license types. This information would include contact information, social security or individual tax payer identification number, the location of the proposed business, and the type of license requested. Within MAUCRSA, the Legislature recognized the current medical cannabis goods marketplace and provided for the issuance of temporary licenses that would allow an applicant to continue operating while they gather the required items for a complete application and while their application is reviewed by the Bureau. The proposed regulations would further explain, specifically, what would be required to demonstrate the pre-conditions set out in MAUCRSA for priority review.

MAUCRSA expressly requires an applicant to provide certain information to the Bureau for processing, including a valid seller's permit issued by the California Department of Tax and Fee Administration, proof of property owner approval for commercial cannabis activity, proof of surety bond, proof of a labor peace agreement if applicable, and fingerprint submission to the Department of Justice. The proposed regulations would further specify what must be submitted to the Bureau related to these items as well as what additional information is required. The proposed regulations would specify that if an applicant submits a license, permit, or other authorization from a local jurisdiction where the premises will be located, then the Bureau will notify the contact person from the local jurisdiction and if the local jurisdiction does not respond within 10 calendar days, the Bureau may approve the application.

The proposed regulations would clarify that applicants shall have, at a minimum, one individual that meets the definition of "owner" under MAUCRSA and would clarify what a "financial interest" in a commercial cannabis business means. The proposed regulations would also clarify that certain individuals such as persons employed by the State of California are prohibited from holding a license when the duties of their employment have to do with the enforcement of MAUCRSA or any other penal provisions of law of this State prohibiting or regulating the sale, use, possession, transportation, distribution, testing, manufacturing, or cultivation of cannabis goods. The proposed regulations would also prohibit persons in district attorney's offices and law enforcement agencies from holding a license.

The proposed regulations would clarify what the premises diagram must show. The proposed regulations would clarify what is required to demonstrate that a landowner has approved use of the premises for commercial cannabis activity. The regulations would also specify the amount of the bond that applicants must have to cover the cost incurred for the destruction of cannabis goods necessitated by a violation of MAUCRSA or the regulations adopted thereunder. The proposed regulations would also specify that applicants or licensees that fall within the scope of sovereign immunity that may be asserted by a federally recognized tribe or other sovereign entity must agree to a limited waiver of sovereign immunity.

The proposed regulations would clarify that applicants must provide proof that their premises is exempt from or in compliance with the California Environmental Quality Act (CEQA). The proposed regulations would also clarify that if an applicant does not have evidence of exemption from or compliance with CEQA that the applicant will be responsible for preparing an environmental document in compliance with CEQA that can be approved or certified by the Bureau.

The proposed regulations would specify that the Bureau may request additional information from the applicant so that the Bureau will have all the necessary information to appropriately evaluate the application for licensure. The proposed regulations would clarify that incomplete applications are abandoned after a specified length of time and that applications may be withdrawn before the Bureau issues or denies a license.

Article 3 of the proposed regulations would provide clarification of special conditions, terms, prohibitions, or requirements, set forth in MAUCRSA that apply to all license types. Specifically, the proposed regulations would clarify the annual license fee for each license type depending on the size of the business. The proposed regulations would also specify how the license fee can be paid. The proposed regulations would clarify the requirements for priority licensing. Additionally, the proposed regulations would clarify which offenses are substantially related to the qualifications, functions, or duties of the business for which licensure is sought and would clarify the criteria for the Bureau to consider in determining whether an applicant that has been sufficiently rehabilitated and is therefore suitable for licensure. The proposed regulations would also provide the specific criteria under which a license can be denied, how the Bureau will notify the applicant that the application was denied, and what the applicant must do to contest the denial.

The proposed regulations would clarify how the Bureau will evaluate whether an excessive concentration of licenses exists in the area of a proposed premises, during application review. The proposed regulations would clarify how a license is renewed and when a license is considered surrendered or cancelled. The proposed regulations would specify when a license is surrendered or canceled. Additionally, the proposed regulations would specify when the Bureau must be notified of a change in the information previously provided to the Bureau, and when those changes require a new application or just notification to the Bureau. The regulations would clarify what happens to the license when the licensee dies or becomes unable to perform the duties associated with the license.

The proposed regulations would clarify that a licensee may have the same licensed premises for two separate cannabis licenses if certain criteria are met, and specify that a licensed premises must not be within a 600-foot radius of a school providing instruction in kindergarten or any grades 1 through 12, day care center, or youth center that is in existence at the time the license is issued and under what circumstances an exemption may be allowed. The proposed regulations would also specify that a licensee cannot make a physical modification that materially or substantially alters the licensed premises from the premises diagram originally filed with the Bureau and clarifies what material or substantial changes are. Further, the proposed regulations would specify that a licensee may not sublet a portion of the licensed premises.

In recognition of the medicinal cannabis businesses that are currently in operation, the proposed regulations would specify a transition period during which time licensees may engage in certain limited activities that are otherwise prohibited under the Bureau's regulations or the regulations developed by the State Department of Public Health. This conduct may be engaged in from January 1, 2018 and before July 1, 2018 and includes the ability of licensees to do business with other licensees irrespective of the M or A designation on the license. Additionally, during the transition period the following may occur: 1) retailers may sell cannabis goods held in their inventory at the time of licensure that are not in child-resistant packaging if they are placed into

child-resistant packaging by the retailer at the time of sale; 2) non-edible cannabis products that do not meet the tetrahydrocannabinol (THC) limits per package set by the State Department of Public Health may be transported and sold; 3) an M-licensee may sell medicinal edible cannabis products that are 10 milligrams of THC per serving regardless of the THC amount in the package; 4) cannabis goods that do not meet labeling requirements prescribed by the Act or the State Department of Public Health may be transported and sold if a sticker with the applicable warning under Business and Professions Code section 26120, subdivisions (c)(1)(A) and (c)(1)(B) is affixed to the cannabis goods prior to sale by a retailer; 5) cannabis goods that have not undergone laboratory testing may be transported and sold if a label stating that they have not been tested is affixed to each package containing the goods prior to sale by a retailer; 6) dried flower held in inventory by a retailer at the time of licensure may be packaged by the retailer into individual packages for sale; and 7) cannabis products held in inventory by a retailer that do not meet the requirements under Business and Professions code 26130 and 26131 and the State Department of Public Health's regulations for ingredients and appearance may be sold by the retailer.

The proposed regulations would provide that a licensee is responsible for the acts of an agent, officer, or other person acting for or employed by the licensee. The proposed regulations would specify that licensees shall not employ or retain persons under 21 years of age. The proposed regulations would clarify that all commercial cannabis activity must be conducted between licensees and that beginning July 1, 2018, A-licensees may only do business with other A-licensees and M-licensees may only do business with other M-licensees. The proposed regulations would specify inventory storage requirements and would also clarify what a significant discrepancy in inventory is. The proposed regulations would also specify when a licensee must notify the Bureau of criminal acts, civil judgements, revocation of a local license, permit, or other authorization, and theft or loss of cannabis goods.

The proposed regulations would specify which business records must be kept, how long they must be kept, and in what manner they must be kept. The proposed regulations would also specify what a licensee may do in case of a disaster such as a fire or flood.

Article 4 of the proposed regulations contains requirements for posting and advertising. The proposed regulations would specify that the licensee must post the license at the licensed premises and clarify where the license must be displayed. The proposed regulations would specify where and when advertising or marketing placed in broadcast, cable, radio, print, and digital communications are allowable as well as specifying that the licensee must provide to the Bureau the audience composition data upon request. The proposed regulations would also specify that any advertising or marketing involving direct, individualized communications must utilize a method of age affirmation to verify that the recipient is 21 years of age or older.

Article 5 of the proposed regulations contains minimum-security requirements that would apply to all licensees. The minimum-security requirements would include a requirement that visitors to a licensed premises be escorted by the licensee or an employee while in the limited-access areas of the premises and would require that employees of the licensee wear identification badges. The proposed regulations would also specify that licensees must use video surveillance systems and would provide the requirements for video surveillance. The proposed regulations would also specify that licensees must ensure that the limited-access areas can be securely locked using commercial-grade, nonresidential door locks and that licensees must use an alarm system at the licensed premises. The proposed regulations would also include a requirement that a retail licensee shall hire or contract for security personnel to provide security services for the licensed premises.

MAUCRSA requires that all cannabis goods be tracked throughout the supply chain. Article 6 of the proposed regulations would specify the requirements for using the track and trace system and reporting the movement of cannabis goods in the system. The proposed regulations would also specify that licensees must reconcile the physical inventory of cannabis goods at the premises with the track and trace records at least once every 14 days. The proposed regulations would also clarify the track and trace requirements for licensees operating under a temporary license, and those in operation at the time of licensure. The proposed regulations would also clarify what a licensee must do if the track and trace system cannot be accessed and the information that must be entered.

Article 7 of the proposed regulations would specify when returns of cannabis goods are permitted. The proposed regulations would also specify how cannabis waste is to be managed. The proposed regulations would also allow returns of defective products between licensees.

Chapter 2: Distributors

The proposed distributor regulations would accomplish three goals: (1) ensuring cannabis goods are properly stored, handled, packaged, and tested; (2) ensuring distributors keep and maintain records that are adequate to effectively track and trace the cannabis goods, thereby assuring that cannabis goods are safe for use by the consumer prior to distribution for retail sale; and (3) ensuring cannabis goods are transported in a safe and secure manner.

First, the proposed regulations would clarify that a distributor may not store or distribute non-cannabis goods on or from the licensed premises. The proposed regulations would require that cannabis goods are properly stored, handled, packaged, and tested. The proposed regulations would allow a distributor to package, re-package, and label or re-label cannabis in the form of dried flower for a licensee. However, the proposed regulations would prohibit a distributor from accepting cannabis goods that have not already been packaged by the manufacturer who manufactured the products, unless the distributor also holds a manufacturing license and is packaging, re-packaging, labeling, or re-labeling its own manufactured cannabis products. The

proposed regulations would also clarify the logistics for laboratory testing and would require the sampling to be recorded on video and the distributors to witness sampling in person. The proposed regulations would clarify when a batch “passes” laboratory testing and when it “fails.” The proposed regulations would specify the steps a distributor must take in conducting final quality-assurance review prior to transporting the cannabis goods to retailers.

Second, the proposed regulations would specify that distributors maintain commercial general liability insurance in the aggregate in an amount no less than \$2,000,000 and in an amount no less than \$1,000,000 for each loss. The proposed regulations would also specify that distributors must conduct inventory reconciliation at least once every 14 days and keep and maintain records specific to distribution and quality-assurance.

Third, the proposed regulations would clarify the requirements for the transportation of cannabis goods, requiring that the cannabis goods are not visible or identifiable during transport, that the cannabis goods are only transported by vehicle, requiring the cannabis goods to be in a secure locked box within the interior of the vehicle, requiring the vehicle to be attended at all times in residential neighborhoods, and requiring all transport vehicles to be equipped with alarm systems. The proposed regulations would specify that certain transport vehicle information must be provided to the Bureau and would set the minimum age for persons in commercial transport vehicles at 21 years of age. The proposed regulations would also require a distributor to submit a shipping manifest to the Bureau and the licensee receiving the cannabis goods prior to transport, and would specify what information a shipping manifest must contain. The proposed regulations would also specify a distributor transport only license which would allow the holder to exercise certain privileges related to transport only. The fees for a distributor transport only license would depend on whether the licensee would transport only the licensee’s product or product for other licensees.

Chapter 3: Retailers

The proposed regulations would specify which individuals may access the retailer premises and limited-access areas. The proposed regulations would require that individuals only be granted access to the retail area to purchase cannabis goods after the licensee has verified that the individual is at least 21 years old, or that the individual is at least 18 years old and possesses a valid physician’s recommendation. The proposed regulations would clarify the hours a retailer may operate, to whom cannabis goods can be sold to, and how cannabis goods may be displayed in the retail area.

The proposed regulations would clarify what goods a licensee may sell, including the provision that licensees may sell non-cannabis products and may sell live immature cannabis plants and seeds if certain requirements are met. The proposed regulations would specify the daily limit of cannabis goods that may be sold to an individual and would clarify that retailers may accept cannabis goods returned by customers. The proposed regulations would prohibit retailers from

providing free cannabis goods to any person, unless certain criteria are met including that the free cannabis is provided only to medicinal cannabis patients. The proposed regulations would also clarify that a retailer may not package or label cannabis goods with the exception that all cannabis goods must be placed into an opaque exit package prior to the customer leaving the premises.

The proposed regulations would also set requirements for delivery and create a license for a non-storefront retailer to conduct retail cannabis sales exclusively by delivery. The proposed regulations would specify that delivery must be: (1) performed by a delivery employee of a licensed retailer; (2) made to a physical address; and (3) made using an enclosed motor vehicle outfitted with a Global Positioning System, vehicle alarm system, and operated by a delivery employee of the licensee. The proposed regulations would specify the amount of cannabis goods that can be carried by a delivery employee of a licensed retailer and that the delivery employee may not consume cannabis goods during delivery. The proposed regulations would also clarify what information must be in a delivery request receipt and what delivery route may be taken.

The proposed regulations would specify that retailers only accept shipments of cannabis goods from a licensed distributor and set requirements for maintaining an accurate record of inventory and performing inventory reconciliation. The proposed regulations would also specify the information a record of sale must contain.

Chapter 4: Microbusiness

Under MAUCRSA, a microbusiness license allows a licensee to conduct multiple commercial cannabis activities under one license. A microbusiness licensee is permitted to: cultivate cannabis on area less than 10,000 square feet; act as a licensed distributor; manufacture cannabis as a Level 1 manufacturer; and/or sell cannabis as a retailer. The proposed regulations would clarify that an applicant may engage in at least three of the four activities: cultivation, manufacturing, distribution, and/or retail sale. The proposed regulations would specify the information that must be provided in the application depending on the commercial cannabis activities the licensee intends to engage in. The proposed regulations would also clarify that microbusiness licensees must comply with all the rules and requirements promulgated for each commercial cannabis activity the licensee intends to engage in. The proposed regulations would clarify that if a licensee decides to change the activities they are authorized to engage in they must submit an application to the Bureau and that any suspension or revocation of a microbusiness licensee may affect all activities performed under that license. Finally, the proposed regulations would clarify specific application requirements for commercial cannabis businesses engaging in cultivation or manufacturing activities. The proposed regulations would also specify additional record keeping requirements for microbusinesses engaging in cultivation and manufacturing.

Chapter 5: Cannabis Events

Under MAUCRSA, state temporary event licenses may be issued, authorizing onsite cannabis sales to, and consumption by, persons 21 years of age or older at a county fair or district agricultural association, provided that certain conditions are met, including that all participants are licensed. The proposed regulations would specify that an applicant for a temporary cannabis event license must first obtain a cannabis event organizer license by submitting an application containing certain information. The proposed regulations would further specify that an application for a temporary cannabis event license must be submitted no less than 60 days prior to the date for which the license is sought and that the license be valid for no more than 4 consecutive days. The proposed regulations would further specify what must be provided with the application including a diagram of the layout of the event with a detailed description of where cannabis sales and consumption will occur, and a list of all licensees that will be providing onsite sales of cannabis goods at the event.

The proposed regulations would specify that all sales of cannabis at a temporary cannabis event may only be performed by a licensed retailer or microbusiness authorized to sell cannabis to retail customers and all cannabis goods to be sold at the event must be transported to the event by a licensed distributor. The proposed regulations would further clarify that cannabis goods sold at a temporary event must comply with all laws and regulations including testing, packaging, and labeling requirements. The proposed regulations would also provide specific requirements for onsite consumption at a temporary cannabis event including that access to the onsite consumption area be limited to persons 21 years of age or older and that cannabis consumption not be visible from any public place or non-age-restricted area.

Chapter 6: Testing Laboratories

Under MAUCRSA, all cannabis goods must meet certain health and safety standards before they can be sold to consumers. To ensure that cannabis goods meet those standards, a representative sample of the cannabis goods must be tested by a licensed testing laboratory. The proposed regulations would provide requirements for the minimum standards for “passing” the statutorily required testing of cannabis goods for retail sale at retailers or microbusinesses. The regulations would also provide the minimum laboratory-operation requirements, which would include requirements such as sampling procedures, personnel qualifications, standard operating procedures, and recordkeeping requirements. These proposed regulations would set forth action levels, threshold values that provide the criterion for determining whether a cannabis goods sample passes or fails an analytical test, that the Bureau considers to be both protective of public health and achievable by the cannabis industry. The proposed exposure limits are necessary to ensure, to the extent feasible, that no cannabis consumer will suffer material impairment of health from exposure to contaminants in cannabis goods. The action levels proposed are for chemicals, foreign material, heavy metals, and microbiological impurities.

Article 1 of the proposed regulations would make clear the applicable meaning of key statutory terms and other terms used within the regulations. These definitions would include terms such as “action level,” “certificate of analysis,” “foreign material,” and “quality control sample.”

Article 2 of the proposed regulations would provide the licensing requirements that are specific to testing laboratories such as proof of ISO/IEC 17025 accreditation, and requirements for obtaining a provisional license if an applicant meets all requirements for licensure apart from the ISO/IEC 17025 accreditation.

Article 3 of the proposed regulations would set forth minimum requirements for the sampling of cannabis goods. These requirements would include: what must be included in a testing laboratory’s sampling standard operating procedures; general sampling requirements such as requirements that the testing laboratory that collects the sample must also perform the required testing; and how samples are to be stored. The proposed regulations would specify that a sample field log must be used to record information related to the sampling. The proposed regulations would also clarify requirements for sampling from a harvest batch and from a cannabis product batch and would require testing laboratories to implement a chain of custody protocol. Additionally, the proposed regulations would specify that a testing laboratory may only accept and analyze samples obtained from a distributor for which there is an accompanying chain of custody form.

Article 4 of the proposed regulations would provide the minimum standards for laboratory standard operating procedures, including procedures for laboratory processes, analytical methods, and testing methodologies. The regulations would also set out what the Bureau considers to be acceptable ways to validate a “nonstandard, amplified, or modified” test method.

Article 5 of the proposed regulations would specify what the laboratory must test for and when testing laboratories must begin testing for certain things. The proposed regulations would specify the standards for the analyses of homogeneity of solid edible cannabis products, moisture content and water activity, residual solvents and processing chemicals, pesticides, microbiological impurities, mycotoxins, foreign material, heavy metals, cannabinoids, and terpenoids. The regulations would also set forth general reporting requirements and require testing laboratories to generate a certificate of analysis for each sample of a batch of cannabis goods that it tests; containing necessary information to identify the testing laboratory, identify the sample, identify the test methods, and provide the test results.

Article 6 of the proposed regulations would provide requirements for post-testing procedures. These requirements would include a requirement that a batch may not be retested following a failed testing unless it has gone through a remediation process, constraints related to remediation, and requirements for retention of the testing sample.

Article 7 of the proposed regulations would set requirements for the minimum components of a quality-assurance program and what must be contained in the quality-assurance manual. The proposed regulations would require the use of laboratory quality control samples which include: method blank, continuing calibration verification, laboratory replicate sample, and matrix spike sample or matrix spike duplicate sample. The proposed regulations would also clarify how to calculate the limit of detection and limit of quantitation and would require licensees to generate a data package for each batch of samples the laboratory analyzes. The proposed regulations would also require proficiency testing, clarify what a satisfactory and unsatisfactory proficiency test is, and require an annual internal audit.

Article 8 of the proposed regulations would specify laboratory employee education and experience requirements. Specifically, the regulations would require that a testing laboratory employ a supervisor or management employee who is responsible for overseeing and directing the scientific methods of the laboratory, ensure the laboratory achieves and maintains quality standards of practice, and provide training to laboratory employees. The proposed regulations would also require that laboratory analysts and samplers meet certain education and experience standards.

Article 9 of the proposed regulations would require testing laboratories licensees to maintain specific records.

Chapter 7: Enforcement

The proposed regulations would specify the enforcement provisions applicable to all Bureau licensees. Specifically, the proposed regulations would provide that the Bureau and its representatives shall have full access to inspect and enter onto any premises licensed by the Bureau. The proposed regulations would specify that the Bureau may provide a notice to comply to a licensee for minor violations observed during the inspection and would specify what a licensee may do in response to the notice. The proposed regulations would provide that the Bureau may issue citations containing orders of abatement and fines against a licensee for any acts or omissions which are in violation of MAUCRSA or its implementing regulations. The proposed regulations would also set forth the procedure for contesting and complying with citations issued by the Bureau.

The proposed regulations would specify the criteria for use of minor decoys including, that the decoy be under 20 years of age and display an appearance which could generally be expected of persons under 21 years of age. The proposed regulations would specify that a license may not be held at a premises where certain attire and conduct is permitted such as employing a person to conduct the sale of cannabis goods while such person is unclothed. The proposed regulations would further clarify that live entertainment is permitted on a licensed premises so long as certain conditions are met.

Under the MAUCRSA, licensees may be disciplined for failure to comply with any of the requirements for licensure that are in the Act itself or in the regulations. The proposed regulations would specify the additional grounds for discipline, such as, failure to take reasonable steps to correct objectionable conditions. The proposed regulations would also specify the procedures for disciplinary actions and would specify that the Bureau may petition for an interim order to suspend a license or impose licensing restrictions in certain cases such as when permitting the licensee to continue to engage in the licensed activity would endanger the public health, safety, or welfare.

The proposed regulations would specify that a premises must post a notice when it has had a license suspended or revoked and would specify what the notice must say and how it must appear. The proposed regulations would clarify that the Bureau may request the administrative law judge to direct the licensee found to have committed a violation to pay a sum not to exceed the reasonable costs of investigation and enforcement of a case and would specify the process for making the request. The proposed regulations would also specify the minimum conditions for probation that must be contained in an order placing a licensee on probation as a condition of staying a revocation or suspension. Lastly, the proposed regulations would specify the disciplinary guidelines to be considered in reaching a decision on a disciplinary action under the MAUCRSA or the Administrative Procedures Act.

Anticipated Benefit of the Proposed Regulations:

The broad objectives of these proposed regulations are to create a state licensed and regulated commercial cannabis market. The proposed regulations are expected to benefit the health and welfare of California residents. The specific benefits anticipated are increased protection of the public and the environment from the harms associated with an unregulated commercial cannabis market. The proposed regulations will ensure that cannabis goods meet health and safety standards by requiring that samples of each batch of harvested cannabis and cannabis products be tested prior to being sold to consumers. The proposed regulations would also ensure that cannabis goods are sold in a manner that prevents access to the goods by persons under the age of 21 who do not possess a valid physician's recommendation.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations:

Under the federal Controlled Substances Act (21 U.S.C. §801 et seq.) cannabis is illegal. However, the U.S. Department of Justice issued guidance regarding the enforcement of cannabis activities in a memorandum issued by Deputy Attorney General James M. Cole on August 29, 2013, commonly referred to as the Cole Memorandum. The Bureau has determined that these proposed regulations are not inconsistent or incompatible with existing regulations or the Cole Memorandum. After conducting a search and review of any similar regulations on this topic, the Bureau has concluded that these are the only regulations that concern the State licensing and

enforcement of commercial cannabis distributors, retailers, microbusinesses, and testing laboratories.

Incorporation by Reference:

The following documents are incorporated into the regulations by reference:

- (1) US Food and Drug Administration's *Bacterial Analytical Manual*, 2016.
- (2) AOAC International's *Official Methods of Analysis for Contaminant Testing of AOAC International*, 20th Edition, 2016.
- (3) United States Pharmacopeia and the National Formulary's *Method of Analysis for Contaminant Testing*, 2016.
- (4) US Food and Drug Administration's *Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition, 2015.
- (5) US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, 2nd Edition, 2015.
- (6) Bureau of Cannabis Control Disciplinary Guidelines November 2017

DISCLOSURES REGARDING THE PROPOSED ACTION

The Bureau has made the following initial determinations:

Mandate on local agencies and school district: None.

Cost or savings to any state agency: None.

Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 et seq.: None.

Other non-discretionary cost or savings imposed on local agencies: None.

Cost or savings in federal funding to the state: None.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS

1. 420Magazine, *How Many Grams/Day is the Average Patient Prescribed* (June 2013) <<https://www.420magazine.com/forums/medical-cannabis-lounge/158520-how-many-grams-day-average-patient-prescribed.html>> (as of Feb. 13, 2017).
2. Agency for Toxic Substances and Disease Registry (ATSDR), *Minimal Risk Levels (MRLs)* (June 2017) <https://www.atsdr.cdc.gov/mrls/pdfs/atsdr_mrls.pdf> (as of Oct. 4, 2017).
3. American Lung Association, *Lung Capacity and Aging* <<http://www.lung.org/lung-health-and-diseases/how-lungs-work/lung-capacity-and-aging.html>> (as of Oct. 4, 2017).

4. Analytical 360, *Moisture Analysis* <<http://analytical360.com/cannabis-analysis-laboratory/interpreting-your-laboratory-data>, 2015> (as of Mar. 28, 2017).
5. Association of Analytical Communities (AOAC), *Guidelines for Single Laboratory, Validation of Chemical Methods for Dietary, Supplements and Botanicals*. 2002. <https://www.aoac.org/aoac_prod_imis/AOAC_Docs/StandardsDevelopment/SLV_Guidelines_Dietary_Supplements.pdf> (as of Mar. 28, 2017).
6. Association of Public Health Laboratories (APHL), *Guidance for State Medical Cannabis Testing Programs* <<https://www.aphl.org/aboutAPHL/publications/Documents/EH-Guide-State-Med-Cannabis-052016.pdf>> (as of Mar. 29, 2017).
7. Antunes, J., et al., *Cystic Fibrosis, Atopy, Asthma and ABPA* (Sept. – Oct. 2010) *Allergologia et Immunopathologia*, 38(5):278-284 <<http://www.elsevier.es/en-revista-allergologia-et-immunopathologia-105-linkresolver-cystic-fibrosis-atopy-asthma-abpa-S0301054610001515>> (as of Mar. 29, 2017).
8. Bennett J.W., et al., *Mycotoxins* (2003) *Clinical Microbiology Reviews*, 16(3):497-516 <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf>> (as of Mar. 28, 2017).
9. Breier, J., Hard Car Security, LLC, *Safety, Transparency and Accountability for the transportation of Cannabis Products and Cash*. (Oct. 2016).
10. Bureau of Cannabis Control, *Pre-Regulatory Meeting Notes* from the following:
 - a. September 19, 2016 – Redding
 - b. September 20, 2016 – Sacramento
 - c. September 22, 2016 – Santa Rosa
 - d. September 26, 2016 – Oakland
 - e. September 27, 2016 – Fresno
 - f. October 4, 2016 – Los Angeles
 - g. October 5, 2016 – San Diego
 - h. October 18, 2016 – Santa Ana
 State of California <<http://www.bmcr.ca.gov/meetings/index.shtml>> (as of Feb. 21, 2017).
11. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Hearing Transcripts on Proposed Medical Cannabis and Testing Laboratory Regulations. Hearing Date June 1, 2017.
12. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Hearing Transcripts on Proposed Medical Cannabis and Testing Laboratory Regulations. Hearing Date June 8, 2017.
13. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Hearing Transcripts on Proposed Medical Cannabis and Testing Laboratory Regulations. Hearing Date June 9, 2017.
14. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Hearing Transcripts on Proposed Medical Cannabis Regulations. Hearing Date June 13, 2017.

15. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Hearing Transcripts on Proposed Testing Laboratory Regulations. Hearing Date June 20, 2017.
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