# 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. The 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.

The proposed regulations are necessary to implement the MAUCRSA and are based on extensive research and outreach by the Bureau. This included: guidance provided from subject matter experts including the University of California Davis Agricultural Issues Center and the California Department of Pesticide Regulation; scientific resources; public comments regarding the Bureau's proposed Medical Cannabis Regulations; federal guidance related to cannabis activity; and information from other states who have legalized cannabis activity such as Oregon, Colorado, Washington, Alaska, and Nevada. Based on all of the research conducted and information received, the Bureau has determined that the specific provisions of the proposed regulations are necessary to effectively implement the MAUCRSA.

## 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

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

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, who has been approved by the local jurisdiction to conduct commercial cannabis activity, to operate 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 preconditions set out in MAUCRSA for priority review.

The 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 2 is necessary to identify the specific information necessary on an application for licensure, which will allow the Bureau to properly determine whether the applicant and proposed premises should be licensed. This includes basic identifying information for the business and its owners, as well as financial information to clearly identify who is involved with the business. This will allow the Bureau to determine the persons responsible for activity conducted under the license and to ensure that the persons with an interest in the license meet all statutory and regulatory requirements. Documentation demonstrating compliance with statutory requirements is required so that the Bureau can confirm these requirements are met by the applicant.

Proposed section 5004 is necessary to clarify what is a financial interest. Business and Professions Code section 26051.5, subdivision (a)(7) requires the applicant for a commercial cannabis license to provide any other information as required by the licensing authority. The regulation clarifies that a financial interest is an investment into a commercial cannabis business, a loan provided to a commercial cannabis business, or any other equity interest in a commercial cannabis business. Proposed subsection (b) provides what the license application shall include for a person with a financial interest in the applicant. Proposed subsection (c) clarifies that banks and other financial institutions that provide loans; individuals whose only financial interest is through an interest in a diversified mutual fund, blind trust, or similar interest; individuals whose only financial interest is a security interest, lien, or encumbrance on property used by the applicant; and individuals who hold a shares of stock less than 5% of the total shares in a publicly traded company, are not

required be listed pursuant to financial interest in the applicant. The Bureau has determined that a person who holds stock in a publicly traded company that is less than 5% of the total shares is similar to a person who holds a security interest due to a lack of direct control over the entity. This 5% threshold is modeled after the Security Exchange Commission ownership reporting threshold. This is necessary to ensure that it is clear that lenders are not owners and therefore not required to apply for the license and submit to background checks.

Proposed section 5006 is necessary to clarify what premises-specific information is required to be included with the application. By requiring a scaled, thorough, and legible diagram, in the application process it will allow the Bureau, to appropriately, and within a reasonable timeframe, evaluate the application for compliance with law. Including the premises information such as boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, windows, doorways, and common or shared entryways will allow for more effective and less disruptive site visits and investigations by Bureau employees. Moreover, including premises information such as entrances, exits, windows, doorways, and common or shared entryways will allow the Bureau to clearly identify the area belonging to the licensee for inspection purposes and public safety. The section also identifies additional requirements for a microbusiness that will engage in cultivation, such as waterways, which are further elaborated on in section 5501 of the division. This information is needed to assist in clearly identifying the boundaries of the cultivation site as well as important characteristics of the land so that the Bureau can ensure the cultivation site meets all legal requirements and that the licensee is the only one in control of the premises. Highlighting and color print on the premises diagram are not allowed as highlighting does not always show in copies and color requires a color copier which are not always readily accessible, therefore black-and-white print will ensure that the diagram is usable if copied.

Proposed section 5009 provides that an applicant or licensee that may fall within the scope of sovereign immunity must waive any sovereign immunity defense. The sovereign immunity defense provides exemptions from certain state laws. This subsection is necessary to ensure that all licensees who engage in commercial cannabis activity are required to follow MAUCRSA and the regulations implementing it. This proposed section will provide for fair and efficient regulation in the cannabis industry, while allowing tribal governments the opportunity to participate in the legal regulated industry. The requirement that a new waiver accompany each license and renewal application will ensure that a valid waiver will be in place for the entire period of the license or renewal. The requirement for the applicant to demonstrate the waiver's signatory has the authority to enter into such an agreement is necessary to ensure the waiver is valid and binds the applicant or licensee to the terms and conditions listed therein. This subsection is necessary to ensure the waiver is a valid executed contract entered into by the tribal government and the Bureau. Proposed subsections (a)(2) - (a)(6) require the tribal sovereignty waiver to include language that clearly states all tribal entity applicants shall conduct all cannabis business activity in full compliance with all state laws and regulations, that the Bureau has access to all licensed areas, access to all records pertaining to commercial cannabis activity, and that all licensees may only sell product to other licensees and customers meeting the legal requirements to purchase cannabis goods. These subsections are necessary to ensure the Bureau has the ability to fully enforce all statutes and

regulations related to the licensing of cannabis business activity and that all cannabis licensees are regulated with the same standards and expectations. Without this specific language it may be unclear which regulations would be applicable to a tribal government creating business and enforcement uncertainty. Proposed subsection (7) clarifies the applicable body of substantive and procedural laws and which legal forum will be used to resolve disputes. Without this language in the waiver it is unclear which court or administrative tribunal is the appropriate forum for redress of claims, which could lead to confusion and delay. This language is necessary to clarify this complex intersection of state, federal, and sovereign immunity law and to avoid conflict of legal jurisdiction and choice of forum for dispute resolution. It also clarifies the applicable law, legal claims, and rights afforded the parties. This provision is necessary to ensure that all matters related to the license issued by the Bureau related to commercial cannabis activity in California will be governed by California law and litigated in California. Proposed subsection (b) specifies that the Bureau will not approve an application for a state license if approval would violate the provisions of any local ordinance or regulation, which is a restatement of the law, under Business and Professions Code section 26055, subdivision (d), and is included to provide clarity. Proposed subsection (c) requires the licensee to notify the Bureau when any material changes have been made to their business entity, their premises, or any other information supplied in their application. Without requiring a licensee to update the Bureau of material alterations of facts there is no assurance the changes are permitted within the statutory and regulatory framework. Without an affirmative duty placed on a licensee to notify the Bureau, a noncompliant change may continue for a significant amount of time before discovery. Placing an affirmative duty to notify ensures the Bureau is kept consistently aware of the shape, condition, and legality of the licensee and licensed premises. This requirement is applicable to other licensees as well; therefore, it is included here for clarity. Proposed subsection (d) clearly states the consequences for statutory or regulatory noncompliance. This subsection is necessary to clarify non-compliance of any of these terms and conditions could lead to denial or discipline of a licensee. This subsection also clarifies that all licensees, tribal governments and non-tribal governments, are governed by the same standards and disciplinary guidelines.

## Article 3

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. 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) or (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 3 is necessary to ensure that the licensees understand requirements for licensure, responsibilities of licensure, and that the Bureau is informed when changes are made related to information contained in the application which impact whether the person or premises should be licensed.

Proposed sections 5014 and 5015 implement the Bureau's authority to collect fees in connection with its regulatory activities under Business and Professions Code section 26012, subsection (b). The fees adopted by the Bureau are based on a recommendation from the economists at the University of California Agricultural Resources Center (AIC), which considered:

- Administrative ease The ease by which a fee could be administered was considered a
  factor in the evaluation of fee options. To reduce administrative costs that impact the ability
  of the Bureau to fully utilize revenue to cover program activities, the fees should not be
  overly burdensome for the Bureau. An efficient fee policy should have minimal
  administrative costs to the Bureau.
- Non-regressive, non-progressive The inherent fairness of a fee was considered a factor in the evaluation of fee options. The variety of businesses suggests variety of fee ranges to absorb the impact of the fees.
- Reflective of administrative cost The extent to which a fee policy reflects the Bureau's costs associated with program workload was considered.

The license fees were determined to be necessary to account for the Bureau's expected total operating costs, which also includes the General Fund loan that was used to establish and support the regulatory activities of the Bureau pursuant to former Business and Professions Code section 19351, and the cost of the licensee's operation of the track and trace system. The license fees are scaled to the size of the business entity licensed, and are based on the costs of services, as well as the potential compensation for each license type. Because regulations and enforcement apply to

both medicinal and adult-use segments equally, no distinction was made between the two, and the same fees were applied to each designation. Subsections (b) and (e) indicate that a license fee must be paid by a licensee or applicant before a license is issued. This language is necessary to clarify when fees must be paid to the Bureau; license fees are condition precedent to license issuance. Subsection (f) provides clarity for prospective licensees regarding whether the license fee is non-refundable. Section 5015 is necessary to provide clarification and guidance on how applicants may pay annual license fees, providing options for applicants on how to make such payments which align with the Bureau's operational ability to accept certain forms of payment.

Proposed section 5016 is necessary to address the information needed by the Bureau to evaluate whether an applicant meets the criteria contained in Business and Professions Code section 26054.2, which requires that in issuing licenses the Bureau shall grant priority in issuing licenses to applicants that can demonstrate the applicant operated in compliance with the Compassionate Use Act of 1996 and its implementing laws before September 1, 2016. The section provides two ways to establish priority, being on a list from the local jurisdiction and providing a document containing specified information. Not all applicants will have preserved specific information related to cannabis activity in anticipation of future state regulation and the industry has only been regulated at the local level, providing alternate methods of meeting this threshold is necessary. Applications will be processed in the order received to allow for efficient processing.

Proposed section 5024 specifies what happens to a license in the event of a licensee's death, incapacity, receivership, assignment for the benefit of creditors of a licensee, or other event rendering a licensee incapable of performing the duties associated with the license. This section is necessary as it provides a licensee's successor in interest the opportunity to transition the licensee's operations and/or handle the licensed business affairs prior to expiration of the license. This regulation provides that though 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. Assuring that a person identified and approved by the Bureau is responsible for the premises and its inventory and that the MAUCRSA requirements are followed is critical to public safety and to prevent diversion into the illegal market.

Proposed section 5029 recognizes that medicinal cannabis businesses are currently in operation and there are not yet adult-use businesses in operation. The Bureau in coordination with the Department of Food and Agriculture and the State Department of Public Health determined that a transition period from January 1, 2018 and before July 1, 2018 was necessary 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. Many cannabis goods currently in the inventory of existing medicinal cannabis businesses do not meet the standards contained in regulations developed by the State Department of Public Health. While many products meet the statutory requirement that edible cannabis products be 10 milligrams of tetrahydrocannabinol (THC) or less per serving, they do not meet the regulatory requirement set by the State Department of Public Health that the products be 100 milligrams or less per package. Additionally, many products currently in inventory do not meet the packaging or labeling

requirements set in regulation, but with the addition of a sticker or secondary child-resistant packaging they would be compliant with statutory requirements. The licensing authorities determined that without a transition period during which these cannabis goods could be transported throughout the supply chain and ultimately sold by the retailer, licensees would have to destroy all the non-compliant cannabis goods. This could result in a substantial financial loss for licensees. Based on stakeholder feedback that packaging is generally ordered six months in advance and the number of cannabis goods that do not meet the THC requirement per package, the licensing authorities determined that a six-month transition period was necessary to allow licensees time to conform to packaging and labeling requirements.

Under MAUCRSA all commercial cannabis activity must be conducted between licensees, and each licensee, except for testing laboratories, must either be designated with an M for medicinal or A for adult-use. Under the proposed regulations licensees are only able to do business with other licensees with the same A or M designation. However, in recognition of adult-use just becoming legal for the first time, there is no adult-use cannabis goods in the currently supply chain. Therefore, to ensure access to product for both the medicinal and adult-use, licensees will need to be able to obtain cannabis goods from other licensees irrespective of the M or A designation on the license.

Proposed section 5038 is necessary, in part to ensure that, pursuant to Business and Professions Code section 26013, subdivision (c), compliance with the regulations is not so onerous that the operation under a cannabis license is not worthy of being carried out in practice by a reasonably prudent businessperson. The Bureau has determined that in certain circumstances a licensee may be relieved from regulatory provisions. Additionally, Government Code section 8571 provides that during a state of emergency the Governor may suspend any regulatory statute, or statute prescribing the procedure for conduct of state business, or orders, rules, or regulations of any state agency, where the Governor determines and declares that strict compliance with any statute, order, rule, or regulation would in any way prevent, hinder, or delay the mitigation of the effects of the emergency. This section would allow licensees that have been impacted by a disaster to be relieved from rules, orders and regulations that would otherwise delay mitigation of the effects of the disaster and the ability to keep cannabis goods secured to prevent diversion in the illegal market and prevent minors from accessing cannabis goods. This section is necessary to allow the Bureau to carry out the implementation and enforcement of MAUCRSA, and the regulation of commercial cannabis activity. Notice of commercial cannabis activity that may be in conflict with MAUCRSA or the regulations should be provided to the Bureau. This section is also necessary to ensure that licensees are provided an opportunity to exercise the privileges of their license, when otherwise prohibited from doing so by forces and circumstances beyond their control, without making compliance with the regulations so onerous that the operation under their license is not worthy of being carried out in practice.

This section is necessary to ensure that licensees who have been impacted by a disaster are not deemed to have surrendered, abandoned, or quit their licenses, due to the impacts of the disaster, if their intent is to continue as a licensee. Additionally, the provisions allowing a licensee to move product to a location different than the original location approved by the Bureau is critical to public safety to ensure that cannabis goods are secured. The Bureau has determined that 24 hours to notify the Bureau is sufficient time for the licensee to immediately secure cannabis goods while providing prompt notice of the change in location to the Bureau. Further, the Bureau has determined that 10

business days is the appropriate time to allow a licensee to provide the Bureau with a request for relief as it allows the licensee time to address the immediate effects of the disaster on the licensee's business while not allowing too much time to elapse before the Bureau can evaluate the proposed plan.

## Article 4

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 4 is necessary to implement the statutory requirements related to advertising. The Bureau has clarified that the licensee must be able to provide data that the target audience of an advertisement meets the statutory percentage for advertisements, and that the licensee must take steps to ensure the recipient is 21 years or older. Requiring the licensee to conduct research about the market will help to prevent violations of the advertising rules and allow the Bureau to determine if the advertisement complies with law. Providing examples of how once can verify age will assist in preventing violations of the MAUCRSA.

## Article 5

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.

The MAUCRSA mandates the Bureau to promulgate regulations that ensure a safe and secure operation of the cannabis goods market. Business and Professions Code section 26011.5 holds that the protection of the public shall be the highest priority for all licensing authorities in exercising licensing, regulatory, and disciplinary functions under MAUCRSA. Business and Professions Code section 26070, subdivision (b) provides that the Bureau shall establish minimum security requirements for the commercial distribution and delivery of cannabis and cannabis products. Business and Professions Code section 26070, subdivision (j) requires licensed retailers and

microbusinesses to implement security measures reasonably designed to prevent unauthorized entrance into areas containing cannabis or cannabis products and theft of cannabis or cannabis products from the premises.

Article 5 is necessary to ensure that licensed premises are locked securely and that cannabis goods do not fall into the hands of minors, non-licensees, or persons who do not meet the requirements to possess cannabis. The proposed security measures will also protect public safety by limiting diversion into the illegal market. Proposed section 5045 is necessary as security personnel will assist in keeping cannabis goods and persons at licensed premises safe. Commercial cannabis businesses operate within certain restrictions, including limitations on receiving financial services through federally insured institutions, like banks. Due to this limitation, many commercial cannabis businesses engage predominantly in cash transactions, and are thus subject to increased security risks. Public comments received from commercial cannabis businesses indicated that many currently in the cannabis market have hired or contracted for security personnel, and believe such security measures are necessary for the safety of their personnel and customers. Unlike other licensees, retailers sell to the public at large, therefore, present a heightened security risk than other licensees. This section is also necessary to provide clarity on the applicable definition of security personnel and ensure any security personnel meet the state requirements for the activities to be conducted as required by the Bureau of Security and Investigative Services.

## Article 6

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 6 is necessary to ensure that information is appropriately entered into the track and trace system to meet statutory requirements for the track and trace system, avoid diversion, audit licensee's activities, ensure cannabis goods have passed testing requirements, and allow for recall of unsafe cannabis goods. Business and Professions Code section 26067 requires the state to develop a track and trace system to record the movement of cannabis. The purpose of the track and trace program is to allow the Bureau and other licensing authorities to track the movement of all cannabis goods as the products move from licensee to licensee and eventually to the customer.

Proposed section 5052 ensures effective tracking of the movement of cannabis goods by identifying the timing of track and trace responsibilities for licensees. Proposed subsection (a) indicates that a temporary licensee is not required to record commercial cannabis activity in the

track and trace system. This section takes into account that temporary licensees will not have had the necessary track and trace training at the time of licensure. Proposed subsection (b) requires all temporary licensees to record all necessary track and trace information, at a minimum, on paper receipts, invoices, or manifests. The requirement that these items be maintained will aid the Bureau in enforcing these regulations, conducting investigations, and preventing diversion and other illegal activity. Proposed subsection (c) requires that all cannabis activity conducted between annual license holders be recorded in the track and trace system. In order for the track and trace system to be effective, all annual licensees must actively participate in the system. Proposed subsection (d) provides that temporary licensees in operation at the time of annual license issuance are required to input track and trace information from the date the account manager attends training forward. This information is to be input no later than 30 days after the track and trace system account manager attends the required training. This section ensures that all information is uploaded by the licensee. It also ensures that the Bureau is provided with all the required information once the track and trace system is operational. This information will allow the Bureau and other licensing authorities to track the movement of all cannabis goods as the products move from licensee to licensee and eventually to the customer.

#### Article 7

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.

Article 7 is necessary to ensure that returns are limited to only defective products to protect consumer safety and ensure that returned products are destroyed appropriately to minimize diversion and to ensure that cannabis waste is handled in compliance with state law related to waste. This will assist with public safety by limiting opportunity for cannabis goods to be diverted into the illegal market at the time of disposal or destruction.

## 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 noncannabis 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.

The proposed regulations in Chapter 2 are necessary to implement and clarify the statutory requirements for distributors. Proposed section 5300 prohibits the distribution or storage of non-cannabis goods, with the exception of cannabis accessories and items used to conduct business, in the distributor's licensed premises. Cannabis goods is defined in proposed section 5000(c) and an item not meeting this definition would be included in non-cannabis goods. This is necessary to ensure public safety by not allowing other non-licensed activities to take place on the premises and to assist Bureau staff and law enforcement during inspections and audits. It is necessary to clearly delineate what may and may not occur on the licensed premises. Because the Bureau does not license non-commercial cannabis activities, it is proposed that such activities be prohibited. This applies to distribution or storage only services and does not prevent a licensee from storing supplies

used in the business, such as office products, toilet paper, receipt books, cleaning supplies, and other similar items.

## **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.

The proposed regulations in Chapter 3 are necessary to implement and clarify the statutory requirements for retailers. Proposed section 5417 subsection (d) requires that all delivery vehicles be outfitted with a device for tracking the vehicle's geographic location. The subsection requires that the device be permanently or temporarily affixed to the vehicle. The subsection also requires

that the device be functioning the entire time the vehicle is making deliveries. It is essential that a licensed retailer have a record of where its delivery vehicles are located at all times and that the Bureau can be provided that information for enforcement and public safety purposes. The device must be affixed to the vehicle at all times during delivery so that the device is not removed from the vehicle while the delivery employee is making a delivery. The device must be owned by the licensee to ensure that the licensee and the Bureau may access the device to determine the vehicle's route. In addition, the device must be exclusively used for delivery so that there is no confusion about when the device is used for commercial cannabis business and when it is used for other purposes not regulated by the Bureau to ensure that the data related to licensed activity is clear. Further, if a delivery vehicle with cannabis goods is reported missing or stolen, it would be beneficial to have a device inside of the vehicle for tracking purposes to assist in recovery of the cannabis goods.

Proposed section 5418 is necessary to mitigate diversion into the illegal and unregulated market, and prevent unauthorized sales. The MAUCRSA mandates the Bureau craft regulations that ensure a safe and secure operation of the commercial cannabis market. The MAUCRSA does not provide clarity as to the permissible amount of cannabis goods that may be sent out of the retailer for delivery. Limiting the amount of cannabis goods that a delivery employee may carry also limits the amount of loss that may occur in the case of theft as well as reducing the risk of consumption during delivery. The Bureau has determined that \$3,000 is an appropriate maximum amount for a delivery employee to carry in the vehicle, allowing for multiple deliveries. Based on an average order of approximately \$100, a delivery person would be able to make approximately 30 deliveries in one trip.

#### 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.

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The proposed regulations in Chapter 4 are necessary to implement and clarify the statutory requirements for microbusinesses. Business and Professions Code section 26070(a)(3) states that a microbusiness is "for cultivation of cannabis on an area less than 10,000 square feet and to act as a licensed distributor, Level 1 manufacturer, and retailer under this division, provided such licensee can demonstrate compliance with all requirements imposed by this division on licensed cultivators, distributors, Level 1 manufacturers, and retailers to the extent the licensee engages in such activities." This section further states that a microbusiness license that authorizes cultivation of cannabis must include certain additional conditions required for a cultivation license issued by the Department of Food and Agriculture. While this section allows a licensee to engage in four commercial cannabis activities, it is vague on how many of the activities a licensee must engage in. The statutory language implies that less than four activities can be engaged in when it states, "to the extent the licensee engages in such activities." Further this interpretation is implied in the last sentence of the statute by specifically referencing additional requirements for a microbusiness license that authorizes cultivation. The last sentence also implies that cultivation is not a required activity by specifically referencing additional conditions a microbusiness would have to comply with if it holds a license that authorizes cultivation. Based on its interpretation, the Bureau determined that it was necessary to require that microbusinesses engage in at least three of the four activities. The reason for this is that cultivation and manufacturing activities are limited in some way under a microbusiness license but the distribution and retailer activities are not. Since the cultivation and manufacturing activities are limited the Bureau decided it was necessary to require that at least one of those activities be engaged in by the licensee, which is accomplished by requiring that at least three of the four activities be engaged in by the licensee. This will ensure that businesses operating under a microbusiness license will engage in most of the allowable activities, including a minimum of one of the limited activities, thus allowing for the vertically integrated activities allowable under a microbusiness license.

# **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 the applicable laws and regulations including testing,

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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 state required testing when 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.

The proposed regulations in Chapter 6 are necessary to implement and clarify the statutory requirements for testing laboratories. The regulations specific to testing labs are based on scientific resources, methods, and theories; generally accepted practices in the laboratory industry; information related to cannabis goods testing in other states; standards for testing any product; public comment; and documents relied upon numbers 1 through 13, 15, 17, 28 through 34, 36 through 42, 44 through 64, 66 through 68, 70 through 76, 80 through 83, 87 through 102, and 105 through 113. The required tests and action levels are consistent with the MAUCRSA statute and information related to the level of health risk when the analytes are consumed.

Specifically, the action levels for pesticides contained in proposed section 5719 are based on the guidelines provided by the Department of Pesticide Regulation, the state agency responsible for regulating the use of pesticides in California. Other action levels are consistent with information from the American Herbal Pharmacopeia, the Cannabis Safety Institute, and other widely accepted guidelines. The standards for testing methods are consistent with guidance for methods of analysis from the United State Food and Drug Administration, the United States Pharmacopeia - National Formulary, and the AOAC International. The widely accepted standards from these organizations are used both in the United States and internationally. Sampling and chain of custody standards are necessary to ensure that sampling is done consistently amongst the various labs within the state, to ensure the accuracy of the testing, and to ensure that the sample has not been tampered with. The personnel requirements are necessary to ensure that the people testing the product have the correct skills and experience for the testing to be valid. These requirements were drafted to be consistent with laboratory job postings for similar positions, the ISO/IEC 17025:2005 standards for all laboratory personnel as licensees are to obtain ISO/IEC 17025 accreditation, and the State of California requirements for research and environmental scientist classifications.

Business and Professions Code section 26100 provides that the Bureau shall develop criteria to determine batch testing. Proposed regulation section 5715 provides criteria for batch testing beginning January 1, 2018. Testing for potency, contaminants with a high public health risk, and contaminants the industry is largely already testing for will begin immediately; followed by testing for contaminants with comparatively moderate health risks and that are not largely being tested for; and finally, by the end of 2018, contaminants with comparatively minor health risks and seldom testing for at this time. This will protect the public while allowing the industry to adjust to new testing requirements so that product will be available to patients and adult-use customers.

## 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 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. The proposed regulations would specify that a license may not be held at some 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.

The proposed regulations in Chapter 7 are necessary to impose discipline or conditions on a licensee to gain compliance with the statutory and regulatory requirements governing licensees. The proposed regulations provide for different paths to address lack of compliance with the law based on the facts and circumstances of a particular situation. This includes a notice to comply, which gives the licensee the opportunity to correct the deficiency within the notice to allow the licensee to come into compliance without a formal disciplinary action when feasible. This allows the Bureau to educate licensees and to assist them with quickly coming into compliance. The proposed regulations also include a citation program, similar to those administered by other licensing entities, which implements the Bureau's statutory authority to address unlicensed activity

to assist in stopping illegal cannabis activity and to correct inappropriate conduct by a licensee at an earlier juncture than filing a formal accusation. The regulations also provide information about proposed penalties for different violations and processes for imposing discipline which place the licensee on notice of the consequences of certain actions and the right to challenge any penalty from the Bureau.

The MAUCRSA allows for the use of minor decoys to ensure that licensees are not selling cannabis goods to persons under 21 years of age. The proposed regulations contain provisions consistent with the Alcoholic Beverage Control's minor decoy requirements. Decoys must be less than 20 years old so that the decoy is clearly under 21 years old. A decoy must carry his or her identification, present this identification if asked, and cannot lie about his or her age if asked by the licensee so that a licensee has a fair opportunity to determine if the minor decoy is under 21 years of age. Finally, the minor decoy must identify the person who sold the cannabis good to him or her so that the proper person is cited.

## 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 *Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition, 2015.
- (2) US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, 2nd Edition, 2015.
- (3) 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) <a href="https://www.420magazine.com/forums/medical-cannabis-lounge/158520-how-many-grams-day-average-patient-prescribed.html">https://www.420magazine.com/forums/medical-cannabis-lounge/158520-how-many-grams-day-average-patient-prescribed.html</a> (as of Feb. 13, 2017).
- 2. Agency for Toxic Substances and Disease Registry (ATSDR), *Minimal Risk Levels (MRLs)* (June 2017) <a href="https://www.atsdr.cdc.gov/mrls/pdfs/atsdr\_mrls.pdf">https://www.atsdr.cdc.gov/mrls/pdfs/atsdr\_mrls.pdf</a>> (as of Oct. 4, 2017).
- 3. American Lung Association, *Lung Capacity and Aging* < <a href="http://www.lung.org/lung-health-and-diseases/how-lungs-work/lung-capacity-and-aging.html">http://www.lung.org/lung-health-and-diseases/how-lungs-work/lung-capacity-and-aging.html</a> (as of Oct. 4, 2017).
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- 5. Association of Analytical Communities (AOAC), *Guidelines for Single Laboratory*, *Validation of Chemical Methods for Dietary, Supplements and Botanicals.* 2002. <a href="https://www.aoac.org/aoac\_prod\_imis/AOAC\_Docs/StandardsDevelopment/SLV\_Guidelines\_Dietary\_Supplements.pdf">https://www.aoac.org/aoac\_prod\_imis/AOAC\_Docs/StandardsDevelopment/SLV\_Guidelines\_Dietary\_Supplements.pdf</a> (as of Mar. 28, 2017).
- 6. Association of Public Health Laboratories (APHL), *Guidance for State Medical Cannabis Testing Programs* <a href="https://www.aphl.org/aboutAPHL/publications/Documents/EH-Guide-State-Med-Cannabis-052016.pdf">https://www.aphl.org/aboutAPHL/publications/Documents/EH-Guide-State-Med-Cannabis-052016.pdf</a> (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 <a href="http://www.elsevier.es/en-revista-allergologia-et-immunopathologia-105-linkresolver-cystic-fibrosis-atopy-asthma-abpa-so301054610001515">http://www.elsevier.es/en-revista-allergologia-et-immunopathologia-105-linkresolver-cystic-fibrosis-atopy-asthma-abpa-so301054610001515</a> (as of Mar. 29, 2017).
- 8. Bennett J.W., et al., *Mycotoxins* (2003) Clinical Microbiology Reviews, 16(3):497-516 <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf</a> (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 <a href="http://www.bmcr.ca.gov/meetings/index.shtml">http://www.bmcr.ca.gov/meetings/index.shtml</a> (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.
- 16. Bureau of Cannabis Control formerly known as "Bureau of Medical Cannabis Regulation" Public Comments on Proposed Medical Cannabis Regulations.
- 17. Bureau of Cannabis Control formerly known as "Bureau of Medical Cannabis Regulation" Public Comments on Proposed Testing Laboratory Regulations.
- 18. Butterfield, D. *10 Strongest Dabs You Can Buy Right Now* (Aug. 31, 2016) Herb <a href="http://herb.co/2016/08/31/strongest-dabs/">http://herb.co/2016/08/31/strongest-dabs/</a> (as of Oct. 4, 2017).

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  <a href="https://www.chp.ca.gov/CommercialVehicleSectionSite/Documents/L%20chp800d.pdf">https://www.chp.ca.gov/CommercialVehicleSectionSite/Documents/L%20chp800d.pdf</a> (as of Feb. 21, 2017).
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  <a href="https://www.chp.ca.gov/CommercialVehicleSectionSite/Documents/chp800c.pdf">https://www.chp.ca.gov/CommercialVehicleSectionSite/Documents/chp800c.pdf</a>> (as of Feb. 21, 2017).
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- 24. California Division of Occupational Safety and Health (Cal/OSHA), *Permissible Exposure Limits (PELs) from Table AC-1*, *Table Z-1* (Jul. 7, 2016) <a href="https://www.osha.gov/dsg/annotated-pels/tablez-1.html">https://www.osha.gov/dsg/annotated-pels/tablez-1.html</a> (as of Mar. 29, 2017).
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