

BUREAU OF CANNABIS CONTROL
CALIFORNIA CODE OF REGULATIONS TITLE 16, DIVISION 42
MEDICINAL AND ADULT-USE CANNABIS REGULATION
INITIAL STATEMENT OF REASONS

SUBJECT MATTER OF PROPOSED REGULATIONS: Medicinal and Adult-Use Cannabis Regulation

SECTIONS AFFECTED: §§5000, 5001, 5002, 5003, 5004, 5005, 5006, 5007, 5007.1, 5008, 5009, 5010, 5010.1, 5010.2, 5010.3, 5011, 5012, 5013, 5014, 5015, 5016, 5017, 5018, 5019, 5020, 5021, 5022, 5023, 5024, 5025, 5026, 5027, 5028, 5030, 5031, 5032, 5033, 5034, 5035, 5036, 5037, 5038, 5039, 5040, 5041, 5042, 5043, 5044, 5045, 5046, 5047, 5048, 5049, 5050, 5051, 5052, 5052.1, 5053, 5054, 5055, 5300, 5301, 5302, 5303, 5303.1, 5304, 5305, 5306, 5307, 5308, 5309, 5310, 5311, 5312, 5313, 5314, 5315, 5400, 5402, 5403, 5403.1, 5404, 5405, 5406, 5407, 5408, 5409, 5410, 5411, 5412, 5413, 5414, 5415, 5416, 5417, 5418, 5419, 5420, 5421, 5422, 5423, 5424, 5425, 5426, 5427, 5500, 5501, 5502, 5503, 5504, 5505, 5506, 5507, 5600, 5601, 5602, 5603, 5700, 5701, 5702, 5703, 5704, 5705, 5706, 5707, 5708, 5709, 5710, 5711, 5712, 5713, 5714, 5715, 5717, 5718, 5719, 5720, 5721, 5722, 5723, 5724, 5725, 5726, 5727, 5728, 5729, 5730, 5731, 5732, 5733, 5734, 5735, 5736, 5737, 5738, 5739, 5800, 5801, 5802, 5803, 5804, 5805, 5806, 5807, 5808, 5809, 5810, 5811, 5812, 5813, 5814, 5815, 5900, 5901, 5902, 5903 and 5904.

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 Bureau held multiple pre-regulatory meetings in late summer/early fall of 2016 and proposed regulations under the MCRSA in April and May of 2017. The Bureau also held regulatory hearings for the proposed MCRSA regulations, which were withdrawn in September of 2017.

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.

On January 1, 2018, the Bureau began issuing licenses for medicinal and adult-use cannabis activities relating to retail, distribution, microbusiness, testing laboratories, and cannabis events. These licensed commercial cannabis businesses are in operation under the emergency regulations adopted on December 7, 2017 and readopted on June 6, 2017.

License Designations – “A” and “M” Commercial Cannabis Activity

In these regulations, the Bureau, along with the Departments of Food and Agriculture and Public Health, propose to allow licensees to conduct business with each other irrespective of their designation as adult-use (A-designated) and medicinal (M-designated) licenses. This allowance will prevent the need for licensees to obtain both an A-designated and an M-designated license and pay twice the license and application fees for the same premises if they wanted to transact both lines of business. These proposed regulations would streamline commerce and reduce paperwork by requiring applicants to obtain a single license and pay one license fee in order to conduct A-designated and M-designated business in one location.

While the MAUCRSA contains a number of requirements for commercial cannabis activity, only a small number of differences exist between A-designated and M-designated licenses – differences that arise only at the customer point of sale. The A-designation or M-designation does not otherwise impact the cannabis cultivation or supply chain. For instance, a retailer must have a license with an M-designation to sell cannabis goods to an individual between 18 and 21 years of age who has a physician’s recommendation. (Bus. & Prof. Code, § 26140, subd. (a).) Similarly, in order to sell cannabis products of a particular per-package THC limit, a retailer must have an M-designated license. (Cal. Code Regs., tit. 17, § 40306.) Indeed, all of the differences between A-designated and M-designated licenses relate only to the retail sale of cannabis goods to adult-use customers versus medicinal customers.

History of the Separate Adult-Use and Medicinal Licenses

Initially, in the emergency regulations adopted on December 7, 2017, the licensing authorities determined that during a transitional period from January 1, 2018 through June 30, 2018, it was necessary to allow A-designated and M-designated licensees to conduct business with each other irrespective of the designation because the adult-use market was new and there would be no place to obtain cannabis goods except for from the existing medicinal market. Following the transitional period, the licensing authorities had prescribed the requirement that A-designated licensees could only do business with other A-designated licensees and M-designated licensees could only do business with other M-designated licensees. For instance, a cultivator with an M-designated license could only sell to a retailer who also possessed an M-designated license.

After noticing the initial emergency regulations, the licensing authorities received feedback from licensees, potential licensees, and the Cannabis Advisory Committee that the transition period should be extended, or the provision allowing licensees to do business with other

licensees regardless of the A-designation or M-designation should be made permanent. Licensees have expressed concerns that if the supply chains are separate for A-designated and M-designated licensees, either supply chain could end up with a shortage or an excess of cannabis goods. In either scenario, licensees and customers may be encouraged to turn to the illicit market to either divert excess cannabis goods or to purchase cannabis goods.

Of note, since the commercial cannabis market began on January 1, 2018, the licensing authorities have not been made aware of any public health or safety threat that has been created during the transitional period as a result of allowing commercial cannabis activity between the market designations. Additionally, requiring two separate licenses for the same activity on the same premises means that licensing authorities must require two applications as well as duplicates of other items, such as the bond required by Business and Professions Code section 26051.5 (a)(10). This inefficient duplication increases costs for the licensing authorities and the licensees. Further, the number of licensed cannabis businesses is still relatively low when compared to the number of businesses in operation before January 1, 2018. The reasons for this are varied, but a substantial contribution is due to the lack of locally-available licenses; many jurisdictions are still developing their local cannabis programs.

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

Continuing to issue licenses with an A-designation and M-designation, and allowing licensees to conduct business with other licensees regardless of the A-designation and M-designation is necessary to avoid increased costs due to the duplication of applications and allows licensees the ability to procure and sell product based on the commercial cannabis market’s demands. This is consistent with Business and Professions Code section 26050, subdivision (b), which requires licensing authorities to affix an A or M on each license.

Nothing in that section prohibits licensing authorities from affixing both designations, and indeed it expressly provides that, with limited exceptions stated in statute, “the requirements for A-licenses and M-licenses shall be the same.” (Bus. & Prof. Code, § 26050, subd. (b).) While licensing authorities do not have discretion to require testing laboratories to have separate A-designated and M-designated licenses, the entities are exercising their discretion to permit the holders of other license types to fill out one application, pay one license fee, and obtain one license rather than insisting on the formality of two licenses, particularly when there are virtually no distinctions between A-designated and M-designated licenses identified by statute. Where MAUCRSA or local ordinances require such a distinction to be made, the Bureau will require an M-designation or A-designation, as appropriate.

REQUIREMENTS APPLICABLE TO ALL APPLICANTS AND LICENSEES

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

With the passage of the MAUCRSA, the Bureau was established to create a comprehensive and coherent regulatory framework for an established industry that had not been comprehensively regulated by the state. While the MAUCRSA provides guidance on the larger macro issues, much of the implementation specifics and clarification of terms were left to the Bureau. There are many terms and phrases that will apply to all Bureau applicants and licensees regardless of license type. These proposed regulations will 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 for licensure; and (3) specific clarification of prohibitions, requirements, or other conditions for compliance with the MAUCRSA.

First, the proposed regulations seek to clarify the applicable meaning of key statutory terms and other terms used within the regulations. These terms include those relevant to requirements of licensees, such as “cannabis waste,” “limited-access area,” “medicinal cannabis patient,” and “retail area.”

Second, the proposed regulations clarify what documents and information are required to complete an application for all license types issued by the Bureau. 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 MAUCRSA also provided for priority review of applications for those applicants that were in operation prior to September 1, 2016. The proposed regulations would further explain, specifically, what would be required to demonstrate the pre-conditions set out in MAUCRSA for priority review.

The MAUCRSA expressly requires an applicant to provide certain information to the Bureau for processing an annual license including, but not limited to: evidence of the applicant’s legal right to occupy the proposed premises for their requested commercial cannabis activity; proof of a labor peace agreement, if applicable; proof of fingerprint submission to the Department of Justice; valid seller’s permit number; proof of a bond;

proof of insurance (for distributors); operating procedures; and a premises diagram. The proposed regulations will specify what must be submitted to the Bureau related to these items.

The regulations will identify additional information required for an annual license such as proof that the premises is exempt from or in compliance with the California Environmental Quality Act (CEQA). The proposed regulations would specify what documents may demonstrate proof and would provide the Bureau's process for reviewing previously prepared environmental documents. The proposed regulations would also specify what an applicant may do if a project is exempt from further environmental review pursuant to CEQA and that if the Bureau determines that a project does not qualify for an exemption, then the applicant will be responsible for the costs of preparation of an environmental document. The regulations will also provide that the Bureau may request additional information from the applicant so that the Bureau will have all of the necessary information to appropriately evaluate the application for licensure. The regulations 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.

The proposed regulations would also clarify special terms, prohibitions, and requirements. Specifically, the proposed regulations include a prohibition that no person holding office in, or employed by, any agency of the State of California or any of its political subdivisions charged with enforcement of the Act, may have any financial interest in a related commercial cannabis business. Without a clear prohibition, both State and local agency staff tasked with the enforcement of the Act could legally own or hold an interest in commercial cannabis business creating a potential conflict of interest. This proposed regulation is necessary to ensure that those tasked with enforcing the Act and criminal laws execute their duties and obligations in a fair and objective manner on behalf of the State of California and any of its political subdivisions.

Third, the proposed regulations provide clarification of special terms, prohibitions, requirements, or conditions set forth in the Act that apply to all license types. Specifically, the regulations contain a provision that a license may be denied for a prior conviction that is substantially related to the qualifications, function, or duties of the business for which licensure is sought. The regulations provide further criteria for the Bureau to consider in determining whether or not an applicant, that has been convicted of a crime that is substantially related to the qualifications, functions, or duties, of the business for which licensure is sought, has been sufficiently rehabilitated and is therefore suitable for licensure. These criteria include the nature of the offense; a person's criminal record as a whole; compliance with the terms set by the court; any act that would allow discipline of a license; whether the activity would have been legal if committed at the time of application; dismissal of a conviction; certificate of rehabilitation; and any other evidence submitted. This allows the Bureau to review the applicant's criminal history and rehabilitation fully to ensure applicants are appropriate for licensure, while not barring licensure due to a conviction without considering other mitigating factors.

The proposed regulations also provide for disaster relief, allowing licenses to reasonably conduct the commercial cannabis activities under emergency situations and conditions

limiting or preventing strict compliance with certain requirements. The proposed regulations also provide for the requirements for record keeping, entry into the track and trace system, security, advertising, and returns and destruction, and apply to all Bureau licensees for consistency purposes. These requirements will assist in preventing theft and diversion into the illegal or unregulated market of cannabis goods, and notifications to the Bureau and law enforcement for inventory discrepancies. The regulations elaborate on requirements related to advertising to assure that all advertising is tailored to appropriately-aged customers. The regulations also have requirements for destruction of cannabis goods to ensure that the products that fail testing, or are discarded, do not end up in the illegal or unregulated market, or are accessible to children, to protect the public safety. As the protection of the public is the highest priority for the licensing authorities, the purpose of these proposed regulatory provisions is to provide a framework within the industry that safeguards public health, safety, and welfare while allowing commercial cannabis businesses to engage in the marketplace.

The regulations also provide that a licensee is responsible for the acts of an agent or employee to ensure that licensees do not violate the MAUCRSA or its implementing regulations by allowing others to act for them. Grounds for disciplinary action against a licensee, in addition to those in the MAUCRSA, are included in the Bureau's regulations to prevent changes to the premises without Bureau approval, denying access to the premises for inspection, and impeding investigations.

DISTRIBUTORS

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

Distributors play a pivotal role in the commercial cannabis supply chain. Ensuring a seamless transition from the cultivation and manufacturing of the cannabis goods through the distribution process is key to a well-regulated market. Prior to MAUCRSA, there was no state regulatory process for the operation of commercial cannabis distributors. The proposed distributor regulations are designed with three main goals: (1) to ensure that commercial cannabis goods are properly stored, handled, packaged, and tested; (2) to ensure commercial cannabis goods are safely and securely transported between licensees; and (3) to ensure distributors keep and maintain records that are adequate to effectively track and trace commercial cannabis goods, thereby helping to prevent entry of untested commercial cannabis goods into the legal market, and diversion of commercial cannabis goods into the illegal or unregulated market. With these goals in mind, the overall purpose of the regulations is to identify the minimum requirements for holding a state distributor license.

The proposed regulations are designed to ensure that commercial cannabis goods are properly stored, handled, packaged, and tested. The proposed regulations explicitly limit the distributor to storing and distributing cannabis goods, cannabis accessories, licensees' branded merchandise, and promotional materials. This is necessary because of the unique circumstances of cannabis being legal to distribute under California law but not federal law. Because cannabis is still illegal to distribute under federal law, the Bureau and law enforcement must be extra diligent to ensure that cannabis goods are properly identified when conducting compliance checks or searches of cannabis goods either at the premises or

in the transport vehicle. It is important to ensure that a distributor is only storing or transporting cannabis goods that came from other licensees and not from the unregulated market. Limiting the items that can be distributed and stored on the premises to cannabis goods and related items, allows for more efficient tracking of cannabis goods by the licensee and by the licensing authorities. Product checks, or searches can be done in a timely fashion so that the distributor is not delayed in moving the goods through the supply chain.

The proposed regulations would explicitly prohibit a distributor from storing live plants. This is necessary because the storing of live plants for a period of time requires the plants to be maintained through watering and potentially through light or sun exposure. This is a problem because the maintenance a plant needs to stay alive is an activity related to cultivation for which only microbusinesses and cultivators licensed by the CDFA are allowed to do. Therefore, the regulations would prohibit a distributor from storing live plants.

The ability of a distributor to package, repackage, and label commercial cannabis goods for a cultivator licensee will allow more efficient and easier flow of commercial cannabis goods through the distribution chain. However, the proposed regulations prohibit a distributor from accepting commercial cannabis goods that have not already been packaged by the manufacturer that manufactured the products. The Bureau believes this provision is necessary to ensure the quality and safety of manufactured commercial cannabis goods. It ensures that packaging takes place in an environment most conducive to good manufacturing practices for packaging. The proposed regulations will also clarify the proper procedures for sampling commercial cannabis goods for testing and clarifies the quality assurance and testing standards applicable to distributors. Because laboratory testing is one of the integral parts of quality assurance for commercial cannabis goods, it is critical to the industry that the regulations be clear and concise. Therefore, the Bureau proposes that distributors witness sampling in person and that it be recorded on video. These requirements would allow the Bureau to verify the sampling process. This requirement helps to prevent situations of nonexistent or improper sampling, intentional tampering with commercial cannabis goods during sampling, and helps to resolve any disputes between licensees that may arise regarding procedures used to sample.

The proposed regulations also ensure that commercial cannabis goods are safely and securely transported between licensees. For example, limiting transport to roadways and requiring that commercial cannabis goods not be visible are requirements that were selected by the Bureau to mitigate intersections with federal law and regulation and will reduce the probability of theft of shipments. Securely locking the product in a box within the interior of the vehicle, requiring alarm systems, and not permitting the vehicle to be left unattended in a residential neighborhood is required in order to discourage theft and other crimes that may threaten public safety. Distributors may not transport any goods except cannabis goods, cannabis accessories, branded merchandise, and promotional materials. However, a distributor may transport commercial cannabis goods from multiple licensees at the same time. The minimum age for drivers and passengers of licensed transport vehicles is 21 years old. The legal age for a person without a physician's recommendation to possess commercial cannabis goods is 21. This requirement helps to ensure that persons who have dominion and control over commercial cannabis goods during transport meet that

age requirement. This provision assists in limiting children's access to commercial cannabis goods. Permitting only a licensee's employees or security personnel to be present during transport discourages diversion and theft and provides the Bureau with the ability to take appropriate action against a licensee for improper activity or malfeasance during transport.

The transport of commercial cannabis goods will require thorough and proper record keeping. A distribution licensee will be required to keep and maintain a load specific shipping manifest, business records, and maintain full integration with the track and trace database. The data includes information about the licensee from whom the goods were received, the type and amount of goods received, the party who holds title to the goods, and the unique identifiers or lot number of the goods. These requirements ensure the commercial cannabis goods stay within the regulated market, preventing untested and potentially unsafe commercial cannabis goods from entering into the system or product being diverted into illegal or unregulated markets. These proposed regulations are necessary to ensure commercial cannabis goods stay within the regulated market. By clearly stating the information distribution licensees are required to have on their shipping manifest, the regulations allow for uniformity of records across distribution licensees and increase the speed and effectiveness of Bureau enforcement investigations.

Lastly, in recognition of the MAUCRSA requirement that only distributors are allowed to transport cannabis goods, the Bureau has created a distribution transport only license. This license allows the holder to transport goods between licensees but does not allow them to conduct the quality assurance review or arrange for laboratory testing. This is necessary because many licensees, especially cultivators, are in remote geographic locations. The distributor transport only license provides flexibility to those licensees that are difficult to reach by allowing them to obtain a distributor transport only license and transport their cannabis to manufacturers or distributors without having to pay a distributor to come to them, which could be quite costly depending on where they are located. This also allows licensees that simply want to transport cannabis goods, but do not want to store them, conduct quality assurance review, or arrange for laboratory testing, to participate in the cannabis marketplace. Because of the importance of quality assurance and laboratory testing, the Bureau has limited the distributor transport only licensee to transporting between cultivators, manufacturers, and microbusinesses with the exception that a distributor transport only licensee may transport immature live plants and seeds from a nursery to a retailer. This exemption is necessary because immature live plants and seeds are not required to be tested and therefore do not need to go through the standard distribution process but must still have a way of reaching the retailer for sale to consumers.

RETAILERS

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

Retailers provide commercial cannabis goods to customers who are the end users of the product. Prior to the MAUCRSA, there was no state regulatory process for the operation of a commercial cannabis retailer. Under the MAUCRSA, the Bureau is responsible for establishing the rules for the operation of commercial cannabis retailers. Without the

regulations developed by the Bureau, there is no set of rules that would apply to all commercial cannabis retailers across the state. The overall purpose of the proposed regulations is to lay out the minimum requirements for holding a state license to operate a commercial cannabis retail premises and are necessary as retailers engage directly with the consumer and the public. The proposed retailer regulations are designed with three main goals.

First, the regulations are designed to ensure that retailers follow the MAUCRSA supply chain requirements. The regulations are designed to require that retailers procure their commercial cannabis goods from licensed distributors. Additionally, the proposed regulations require that retailers use the track and trace system to monitor activity. The proposed regulations will also require that the retailers ensure that they only provide commercial cannabis goods to individuals who are legally allowed to purchase them. This is achieved by requiring that all potential customers provide the retailer with identification and a physician's recommendation (if required). The proposed regulations also ensure that customers will have access to commercial cannabis goods by setting requirements for delivery.

Second, the regulations are designed to protect public health and safety. The proposed regulations require that retailers only sell commercial cannabis goods that have undergone required testing procedures. The proposed regulations also prohibit a retailer from packaging commercial cannabis goods on-site, which leads to a reduction in the risk of contamination or adulteration after the mandated state testing process. The regulations prohibit the consumption of commercial cannabis goods by delivery employees while they are performing deliveries. The proposed regulations also require that commercial cannabis goods be stored in a manner to prevent spoilage or degradation. The proposed regulations prevent a retailer from reselling any commercial cannabis goods that have been returned by a customer. Additionally, the proposed regulations require that commercial cannabis goods be placed in a resealable child-resistant opaque exit package before leaving the premises or providing the goods to a delivery customer. The exit packaging will make it more difficult for young children to gain access to the commercial cannabis goods. Limits on daily sales to an individual customer reflect the limits under the Health and Safety Code so that a retailer does not allow a person to purchase more than the amount he or she can legally possess.

Third, the proposed regulations are designed to limit the risk of diversion. The proposed regulations have strict security requirements regarding who may access the retail premises or delivery vehicles. The proposed regulations limit the amount and placement of commercial cannabis goods used for display. The proposed regulations require that retailers only be open for sales between the hours of 6:00 a.m. and 10:00 p.m. in order to reduce the increased risk of robbery and other crimes and comply with certain security requirements when not open for business. The proposed regulations impose rules on who can perform deliveries, the time during which deliveries can be made, and how deliveries are to be performed to reduce risk of crime. Under the proposed regulations, retailers are required to closely monitor their inventory of commercial cannabis goods by doing inventory

reconciliation activities and meeting certain recordkeeping requirements. The proposed regulations also allow for retailer to retailer transfer, under the same ownership, and by a licensed distributor.

MICROBUSINESSES

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

Microbusinesses enable licensees to engage in multiple commercial cannabis activities under one license: cultivate commercial cannabis on an area less than 10,000 square feet; act as a licensed distributor; manufacture commercial cannabis as a Level 1 manufacturer; and/or sell commercial cannabis as a retailer. Prior to MAUCRSA, there was no state regulatory process for the operation of a vertically integrated microbusiness. Under the MAUCRSA, the Bureau is responsible for establishing rules for the operation of microbusinesses. Without the regulations developed by the Bureau, there is no set of rules that would apply to all vertically-integrated microbusinesses operating statewide. The overall purpose of the proposed regulations is to lay out the minimum requirements for holding a state license to operate a microbusiness. The proposed microbusiness regulations are designed with two main goals: (1) clarifying what documents and information is required to complete an application for a microbusiness license; and (2) ensuring microbusiness follow the MAUCRSA supply chain requirements for all commercial cannabis activities they will be engaging in.

Because MAUCRSA is silent as to the license application requirements for microbusinesses, 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. MAUCRSA does not specify how many commercial cannabis activities a microbusiness must conduct to be eligible for licensure; the proposed regulations would clarify that an applicant must 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 such as requiring a cultivation plan and supplemental water source information if the licensee will engage in cultivation. The proposed regulations would specify that if a microbusiness' cultivation is found to be causing significant adverse impacts on the environment in a watershed or other geographic area, the Bureau shall not issue any new microbusiness licenses that include cultivation for that area. For manufacturing activities, the proposed regulations would require a description of inventory control procedures, quality control procedures, security procedures, and waste procedures as part of an application for microbusiness licensure.

Recognizing that each commercial cannabis activity has distinct operational requirements, 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 specify that the areas of the premises for manufacturing and cultivation shall be separated from the distribution and retail areas by a wall and all doors between the areas shall remain closed when not in use.

The proposed regulations would clarify that if a licensee decides to change the activities they are authorized to engage in they must submit a request for modification to the Bureau and that any suspension or revocation of a microbusiness licensee may affect all activities performed under that license. The proposed regulations would also specify additional record keeping requirements for microbusinesses engaging in cultivation and manufacturing. Although bound to the Bureau's general recordkeeping requirements, manufacturing and cultivating activities have distinct records tailored to the nature of their operations. These requirements will assist in preventing theft, diversion into the illegal or unregulated market of commercial cannabis goods and tracking of movement of commercial cannabis goods. The proposed recordkeeping provisions for microbusinesses assure that all licensees conducting the same commercial cannabis activities maintain similar records for Bureau review and inspection.

CANNABIS EVENTS

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

Under MAUCRSA, state temporary event licenses may be issued, authorizing onsite commercial 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. Prior to MAUCRSA, there was no state regulatory process for conducting temporary cannabis events. Under the MAUCRSA, the Bureau is responsible for establishing rules for the operation of temporary cannabis events at a county fair or district agricultural association. Without the regulations developed by the Bureau, there is no set of rules that would apply to all temporary cannabis events statewide. The overall purpose of the proposed regulations is to lay out the minimum requirements for the operation of a temporary cannabis event, licensed by the Bureau.

First, the proposed regulations would specify the application requirements for individuals or entities interested in holding a temporary cannabis event. Anyone interested in holding a temporary cannabis event must first apply to the Bureau as a temporary cannabis event organizer; this ensures that only licensees that are pre-approved by the Bureau are applying for temporary cannabis event licenses. It also reduces the amount of information the Bureau will need to collect from an applicant for each temporary cannabis event. The proposed regulations would 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. This assures that the Bureau has adequate time to review information submitted by the applicant, and collect additional information, as needed. The proposed regulations also provide that a temporary cannabis license shall be valid for no more than 4 consecutive days, providing clarity to applicants regarding the temporal constraints of temporary cannabis event licensure. The proposed regulations would specify what must be provided with the application, including a diagram of the layout of the event with a detailed description of where commercial cannabis sales and consumption will occur. Similarly, applicants must provide the Bureau and a list of all licensees that will be providing onsite sales of commercial cannabis goods at the event at least 72 hours before the event. The proposed regulations would also specify that the cannabis event organizer provide a

designated contact person(s) who shall be onsite at the event and reachable by telephone at all times that the event is occurring. These requirements ensure that the Bureau and its enforcement staff have all information necessary to effectively evaluate whether licensees are operating in a manner consistent with MAUCRSA and its implementing regulations.

Further, the proposed regulations would specify certain operational requirements that must be met by temporary cannabis events to ensure public health and safety for event attendees. Specifically, the proposed regulations require that all temporary cannabis event sales of commercial cannabis only be performed by a licensed retailer or microbusiness authorized to sell commercial cannabis to retail customers and all commercial cannabis goods to be sold at the event must be transported to the event by a licensed distributor. The retail sales must be conducted within their assigned areas, and prohibits mobile sales. The proposed regulations would further clarify that commercial cannabis goods sold at a temporary event must comply with the applicable 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.

TESTING LABORATORIES

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

The MAUCRSA mandates that protection of the public be the highest priority for all licensing authorities. In keeping with that, the MAUCRSA requires that the Bureau develop procedures for ensuring that all cannabis goods are tested prior to distributing them to a retailer. The MAUCRSA requires that all cannabis goods be tested by testing laboratories licensed by the Bureau. Through the proposed regulations, the Bureau aims to ensure the cannabis goods sold to consumers are safe for human consumption. The Bureau also aims to ensure consumers receive accurate information regarding the cannabis goods they consume.

First, the MAUCRSA requires the Bureau to develop regulations for testing the chemical profile of cannabis, including THC, THCA, CBD, CBDA, terpenes, CBG, CBN and any other compounds or contaminants as determined by the Bureau. Additionally, the MAUCRSA mandates the Bureau to establish levels for contaminant including residual solvents, foreign material, and microbiological impurities. Contamination may occur during various stages of the cultivation, harvest, extraction, processing, and packaging. Some of the types of contamination that can make cannabis goods unsafe includes residual pesticides, residual solvents and processing chemicals, microbiological impurities, heavy metals, and foreign material. These proposed regulations aim to establish action levels that the Bureau considers are 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 consumer will suffer material impairment of health from exposure to contaminants in cannabis goods. As such, these contaminants are discussed in greater detail:

Chemicals

During the cultivation and manufacturing process, injurious chemicals can contaminate cannabis goods. For instance, solvents are used to extract, in concentrated amounts, cannabinoids from dried flower. Some of the chemicals used as solvents may linger after the processing is finished. When present in products intended for human consumption, excessive amounts of these residual solvents and processing chemicals may pose risks to human health.

Microbiological impurities

Some *Escherichia coli* (*E. coli*) strains can cause human disease. One strain produces a toxin called Shiga toxin, which can result in serious illness. Because of the low infectious dose required for disease causation, the Bureau proposes there be zero tolerance for the presence of Shiga toxin-producing *E. coli* in cannabis goods.

In addition, the presence of *Salmonella* in cannabis has been documented and, in 1981, resulted in a multistate outbreak. It has also been associated with gastrointestinal disease in both healthy and in immunocompromised populations. The Bureau proposes testing for all *Salmonella* strains.

There have been a number of cases involving immunocompromised people who have become ill, or died, from inhaling *Aspergillus*. *Aspergillus* is a fungus that can cause serious health problems. Certain *Aspergillus* strains can cause a variety of immune-reaction lung disorders, ranging from asthma, allergic bronchopulmonary aspergillosis, and hypersensitivity pneumonitis to invasive systemic fungal infections. The Bureau proposes testing for this fungus.

Mycotoxins

Mycotoxins are toxic substances produced by certain fungi that can grow on human food and animal feed grain. Human exposure to mycotoxins, through ingestion, inhalation, and dermal contact, has been associated with severe human health impacts that include necrosis, cirrhosis, and carcinomas. The Bureau proposes requiring testing for certain mycotoxins.

Foreign material

Medical cannabis products may be injurious to health if they consist in whole or in part of any filthy, putrid, or decomposed substances or is otherwise contaminated by any added poisonous or added deleterious substance. This may occur if the cannabis goods have been stored, prepared, or packed under unsanitary conditions. The Bureau proposes requiring testing for foreign material.

Heavy metals

Cannabis plants are known to uptake metals from contaminated growth media (for example, soil), which increases the risk of adverse health effects associated with the consumption of cannabis goods. For example, exposure to lead may cause neurological, reproductive, developmental, immune, cardiovascular, and renal health effects. And mercury shows toxicological effects such as neurological, corrosive, hematopoietic, and

renal effects as well as cutaneous disease (acrodynia). The Bureau proposes requiring testing for heavy metals.

Second, the proposed regulations set minimum standards for testing laboratories. The MAUCRSA requires that testing laboratories conduct in a manner consistent with general requirements for the competence of testing and calibrations activities, including sampling and using verified methods. There are inherent challenges to regulating an industry that has not been federally regulated and has only been newly regulated in other states. With regard to cannabis testing laboratories, one challenge the Bureau faced when developing these proposed regulations was lack of generally accepted verified methods for the testing of cannabis goods. Therefore, it was imperative the Bureau include regulations regarding verification of testing methods. Additionally, because ISO/IEC, the joint technical committee that establishes the accreditation requirements that the testing laboratories are subject to, is a private organization not under the control of the Bureau, nor subject to public-record disclosure laws, it was necessary for the Bureau to develop its own minimum standards for laboratories. These standards aim to ensure that the laboratories that test cannabis goods before retail sale adhere to laboratory practices that result in accurate information being provided to consumers about the contents of the cannabis goods. These proposed standards would enable the Bureau to ensure that laboratories maintain high operational standards and conduct valid tests. These testing laboratory standards include ones for sampling procedures, test method validation, quality assurance, and laboratory personnel qualifications and are discussed in greater detail:

Sampling

Proper sampling collection may be far more consequential than laboratory measurement errors. If a sample of cannabis goods is improperly obtained, the measurement data that is gathered through analyzing the sample puts the measurement data it produces into question. Proper sampling is therefore critical to obtaining relevant and valid data.

In these regulations, the Bureau proposes fairly detailed minimum sampling requirements. These requirements include what must go into a testing laboratory's sampling protocol and how samples are to be stored.

Validation of Test Methods

An analytical procedure is developed to test a defined characteristic of a substance against established acceptance criteria for that characteristic. This is called a "method," or a "test." To ensure the method used results in reliable, valid data, the method must be "validated" before it is used to produce usable results. Method validation is a process by which a method is tested to ensure it is producing valid results.

Because it is only fairly recently that laboratories begun to test cannabis goods for potency and contamination, and because the federal government does not regulate this industry, there are few validated methods for the testing of cannabis goods. Therefore, laboratories will have to validate their own methods for the testing of cannabis goods.

The laboratory's analytical instrumentation and methodology should be selected based on the intended purpose and scope of the analytical method. Parameters that may be evaluated during method development are specificity, linearity, limits of detection (LODs) and limits of quantitation (LOQs), range, accuracy, and precision.

These proposed regulations set out what the Bureau considers to be acceptable ways to validate a "nonstandard" method, which will be used for testing cannabis goods. In developing these proposed method validation regulations, the Bureau looked to guidelines and other resources used in other industries.

Quality Assurance

Quality assurance is a set of operating principles that enable laboratories to produce defensible data of known accuracy and precision. These operating principles form a laboratory quality assurance program and are documented in a laboratory's quality assurance manual. These regulations propose the minimum components of a quality assurance program and quality assurance manual.

The Bureau's proposed quality assurance program includes requirements for quality control samples. The Bureau proposes to require the use of laboratory quality control samples including method blank samples, laboratory replicate samples, and matrix spike samples. The proposed regulations also set out how to calculate the limit of detection and limit of quantitation. They also specify recordkeeping requirements and require an annual internal audit. Together these proposed regulations will assist in providing accurate testing and guidance for how to ensure accurate testing.

The Bureau is also proposing required proficiency testing. Proficiency testing is an objective assessment of a laboratory's ability to perform analyses. The Bureau proposes requiring testing laboratory licensees participate in a proficiency testing program provided by an organization that operates in conformance with the requirements of ISO/IEC 17043 so that every analyst and every method used by the laboratory is eventually tested. This is an important check on the ability of laboratories to provide accurate data.

Personnel

The education and experience level of the personnel of a testing laboratory is very important. Many of the required tests in these proposed regulations are complex and must be done by persons with specialized training. Therefore, the Bureau proposes in these regulations to require testing laboratories licensed by the Bureau to have a laboratory supervisor or management staff. It is also proposed that any employee who performs analytical tasks meet some minimum qualifications. This is done to ensure laboratories are run by competent and trained persons, to ensure accurate testing, and to ensure public safety.

ENFORCEMENT

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

Under the Act, each licensing authority has the power to create, issue, deny, renew, suspend, revoke, place on probation with terms and conditions, or otherwise discipline a

licensee for any acts or omissions constituting grounds for disciplinary action. The Act does not provide a comprehensive list of grounds for disciplinary action, and does not provide for specific enforcement actions falling short of discipline, or a specific process to challenge an enforcement action that is not appealable to the Cannabis Control Appeals Board, under Business and Professions Code section 26040 et seq. While the Act provides guidance on the larger macro issues, much of the implementation specifics and clarification of terms was left to the Bureau. Under the Act, the Bureau is responsible for establishing the regulatory framework for disciplinary action for certain licensed and unlicensed commercial cannabis activities. Without the regulations developed by the Bureau, there is no set of rules that would apply to Bureau licensees statewide. The overall purpose of the proposed regulations is to lay out strong and fair enforcement provisions, to ensure that there is a balance between allowing for the feasible operation of cannabis businesses, while deterring illegal and criminal activities.

Moreover, the proposed regulations will establish a framework for which the Bureau will initiate or undertake enforcement action, including disciplinary action. Enforcement of the Act is essential to carrying out the duties of the Bureau in ensuring the protection of the public as the highest priority. All enforcement actions, and disciplinary actions, are taken with this statutory mandate in mind. These proposed regulations will provide the requirements and procedures necessary to ensure that the Bureau is engaging in actions that are necessary and fair. It is important to ensure that the Bureau's enforcement actions will not be compromised, while affording licensees their rights to due process. To the extent necessary, these proposed regulations will provide the Bureau's inspection process, and will clarify the Bureau's right to access information and materials pursuant to the Act. The proposed regulations will also provide an overview of the process for issuing citations and monetary fines, as a method of ensuring licensee compliance with the Act and its implementing regulations, short of taking disciplinary action. The proposed regulations will also enable the Bureau to provide notices of compliance, that are intended to advise licensees on abatement of violations that do not rise to the level of citation issuance or disciplinary action. Under the proposed regulations, the Bureau will also have the authority to issue emergency decisions and orders, in circumstances where immediate action is necessary in order to safeguard public health, safety, and welfare. The proposed regulations provide the procedures for temporary, interim relief, before and after issuance of such an emergency decision and order.

The enforcement actions and prohibited acts under these proposed regulations will ensure a safe and efficient market for commercial cannabis activity.

The proposed regulations also provide clarity regarding certain activities that are prohibited on the licensed premises. This will aid licensees, applicants, and the public to mitigate the risk for possible criminal activities. The current lack of a banking system for commercial cannabis has resulted in a historically cash-heavy industry that may be subject to a higher risk of criminal activity than other industries. The proposed regulations provide clarity to mitigate such potential risks, thereby ensuring protection of the licensee and public to the extent possible.

OTHER PROVISIONS

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

The Act, under Revenue and Taxation Code section 34019, subsection (b), provides that a sum of ten million dollars (\$10,000,000), will be disbursed annually to public universities in California, beginning with the 2018-2019 fiscal year until the 2028-2029 fiscal year, to research and evaluate the implementation and effect of the Act. While the Act provides the Bureau the authority to select the universities that will be eligible for this disbursement, much of the implementation specifics was left to the Bureau. Specifically, the Act does not provide the process for application and selection, or the specific criteria for selecting universities to receive the enumerated funds. Accordingly, the purpose of the proposed regulations is to implement, interpret, and make specific Revenue and Taxation Code section 34019, subsection (b), and the duty of the Bureau to make selections for funding on research related to cannabis use, so that the public will have access to useful knowledge on a new industry and product that has not widely been researched or evaluated.

The research contemplated under the Revenue and Taxation Code, section 34019, and this division, will focus on the efficacy of the rules and regulations carried out under the Act, as well as the public health and safety of cannabis use, and the economic impacts of cannabis use and licensing. The proposed regulations will detail the selection criteria and process by which the Bureau will select eligible universities for funding. It will provide for the process and requirements for funding, which is necessary to ensure the funds will be properly allocated and efficiently used to satisfy statutory mandates. The proposed regulations will also require selected universities to satisfy performance reporting standards and provide annual reports to further ensure that research is aligned with the statutory provisions, while providing the public up-to-date knowledge on this developing industry.

SPECIFIC PURPOSE, NECESSITY, AND RATIONALE FOR EACH ADOPTION

The Bureau proposes to add sections §§ 5000, 5001, 5002, 5003, 5004, 5005, 5006, 5007, 5007.1, 5008, 5009, 5010, 5010.1, 5010.2, 5010.3, 5011, 5012, 5013, 5014, 5015, 5016, 5017, 5018, 5019, 5020, 5021, 5022, 5023, 5024, 5025, 5026, 5027, 5028, 5030, 5031, 5032, 5033, 5034, 5035, 5036, 5037, 5038, 5039, 5040, 5041, 5042, 5043, 5044, 5045, 5046, 5047, 5048, 5049, 5050, 5051, 5052, 5052.1, 5053, 5054, 5055, 5300, 5301, 5302, 5303, 5303.1, 5304, 5305, 5306, 5307, 5308, 5309, 5310, 5311, 5312, 5313, 5314, 5315, 5400, 5402, 5403, 5403.1, 5404, 5405, 5406, 5407, 5408, 5409, 5410, 5411, 5412, 5413, 5414, 5415, 5416, 5417, 5418, 5419, 5420, 5421, 5422, 5423, 5424, 5425, 5426, 5427, 5500, 5501, 5502, 5503, 5504, 5505, 5506, 5507, 5600, 5601, 5602, 5603, 5700, 5701, 5702, 5703, 5704, 5705, 5706, 5707, 5708, 5709, 5710, 5711, 5712, 5713, 5714, 5715, 5717, 5718, 5719, 5720, 5721, 5722, 5723, 5724, 5725, 5726, 5727, 5728, 5729, 5730, 5731, 5732, 5733, 5734, 5735, 5736, 5737, 5738, 5739, 5800, 5801, 5802, 5803, 5804, 5805, 5806, 5807, 5808, 5809, 5810, 5811, 5812, 5813, 5814, 5815, 5900, 5901, 5902, 5903 and 5904 of Division 42 of Title 16 of the California Code of Regulations, as follows.

§ 5000. Definitions

Subsection (a) defines “Act” as the Medicinal and Adult-use Cannabis Regulation and Safety Act. This is necessary because “Act” is used throughout the regulations.

Subsection (b) defines “Bureau” as the Bureau of Cannabis Control, previously named the Bureau of Marijuana Control, the Bureau of Medical Cannabis Regulation, and the Bureau of Medical Marijuana Regulation. This is necessary because “Bureau” is used throughout the regulations.

Subsection (c) defines “cannabis accessories” as having the same meaning as in Health and Safety Code section 11018.2. This definition is necessary because “cannabis accessories” is used throughout the division, and a definition will provide clarity to the licensees. The definition chosen is consistent with that already in law.

Subsection (d) defines “cannabis goods” as cannabis, including dried flower, and products containing cannabis. This is necessary to provide a means to refer to cannabis, dried flower, and manufactured cannabis products in a short and succinct way.

Subsection (e) defines “cannabis waste” as waste that is not hazardous waste, as defined in Public Resources Code section 40141, and is organic waste, as defined in Public Resources Code section 42649.8 (c), that contains cannabis and that has been made unusable and unrecognizable in the manner prescribed in sections 5054 and 5055 of this division. This definition is necessary to clarify under what circumstances cannabis goods are considered “cannabis waste” and must be handled accordingly. This definition was also based on feedback from Cal Recycle and was developed in coordination with proposed regulations promulgated by the California Departments of Food and Agriculture and Public Health.

Subsection (f) defines “canopy” as the designated area(s) at a licensed premises that will contain mature plants at any point in time. Business and Professions Code section 26070(3)(A) provides that microbusinesses may only engage in the cultivation of cannabis on an area less than 10,000 square feet. To assure that microbusinesses are operating in a manner consistent with the Act, section 5502 of this division requires microbusiness applicants to disclose all of their cultivation activities, including their canopy, as part of their applications for licensure. The proposed definition is added to clarify the statutory reference to canopy throughout the Act, so that prospective microbusiness licensees that wish to engage in cultivation activities under their license know how to calculate canopy in their applications for licensure.

Subsection (g) defines “delivery employee” as an individual employed by a licensed retailer or microbusiness who delivers cannabis goods from the licensed retail premises to a qualified customer or primary caregiver at a physical address. The term delivery employee requires a definition because delivery employees need to be differentiated from the other employees of the licensee. There are a number of regulations that only apply to delivery employees due to the unique duties of an employee who delivers cannabis goods. In order to avoid confusion with employees who do not perform deliveries, the term delivery employee is used throughout the regulations.

Subsection (h) defines “free cannabis goods” as any amount of cannabis goods provided to any person without cost or payment or exchange of any other thing of value. The term free cannabis goods requires a definition because free cannabis goods may only be provided in very specific circumstances to ensure compliance with the Act.

Subsection (i) defines “kief” as the resinous trichomes of cannabis that have been separated from the cannabis plant. This term is necessary because it provides clarity regarding a form of cannabis that is often used in pre-rolls.

Subsection (j) defines “limited-access area” as an area in which cannabis goods are stored and is only accessible to a licensee and a licensee’s employees and contractors. This term is necessary to clearly delineate higher security areas on a licensed premises as required by the Act.

Subsection (k) defines “lot number” or “batch number” as a distinctive group of numbers, letters, or symbols or any combination of these that is unique to a group of cannabis goods. This section is necessary to clarify what a batch number or lot number is. Batch is defined in the MAUCRSA under Business and Professions Code section 26001(d) as a specific quantity of homogenous cannabis or cannabis product that is one of a number of types of cannabis or cannabis products. Lot is also defined in the MAUCRSA under Business and Professions Code section 26001(ad) as a batch or a specifically identified portion of a batch. Both batch and lot are terms regularly used by testing laboratories to identify the group of cannabis goods from which a sample is used. In order to track the batches the Bureau’s proposed regulations on distributors and testing laboratories require that a batch number be assigned to the batch and listed on the certificate of analysis. This section is necessary to clarify what a batch number or lot number is so that licensees know how to indicate distinct batches for tracking purposes.

Subsection (l) defines “medicinal cannabis patient” to include a qualified patient as defined in Health and Safety Code section 11362.7 and a person in possession of a valid identification card issued under Health and Safety Code section 11362.71. This definition is necessary because “medicinal cannabis patient” is used throughout the Bureau’s regulations to identify customers that are eligible to purchase cannabis goods that are intended for medicinal use only. The definition chosen is consistent with provisions already in law.

Subsection (m) defines “nonvolatile solvent” as any solvent used in the extraction process that is not a volatile solvent and includes carbon dioxide used for extraction. This definition was developed in coordination with proposed regulations promulgated by the California Department of Public Health and is being adopted here for consistency.

Subsection (n) defines “package” and “packaging” as any container or wrapper that may be used for enclosing or containing any cannabis goods for final retail sale. This definition specifies that “package” and “packaging” do not include a shipping container or outer wrapping used solely for the transport of cannabis goods in bulk quantity to a licensee. This definition is necessary because “package” and “packaging” are reoccurring terms within this proposed regulation. The definition is consistent with regulations promulgated by the California Department of Public Health who is primarily responsible for packaging and labeling requirements under the Act.

Subsection (o) defines “pre-roll” as any combination of the following in paper: flower, shake, leaf, or kief that is obtained from accumulation in containers or sifted from loose,

dry cannabis flower or leaf with a mesh screen or sieve. Licensed distributors have the ability to package, re-package, label, and re-label cannabis, including pre-rolls; this definition is necessary because it provides added clarity regarding what a pre-roll may be comprised of.

Subsection (p) defines “publicly owned land” as any building or real property that is owned by a city, county, state, federal, or other government entity. The term publicly owned land is used in the proposed regulations in the context of forbidding licensed retailers from delivering to publicly owned land. This definition is necessary to specify that the term applies to land owned by any government. It is vital that licensees fully understand which properties are considered to be publicly owned and which are not in order to be aware of where they are allowed to make deliveries of cannabis or cannabis products.

Subsection (q) defines “residential area” as an area that is within 600 feet of any single-family or multifamily residence, other than commercial hotels, motels and similar establishments for temporary lodging. This definition is necessary to delineate the scope of area qualified as residential area. This definition is an amalgamation of local ordinances and Section 11362.768 of the Health and Safety Code.

Subsection (r) defines “retail area” as a building, room, or other area upon the licensed retailer or microbusiness premises in which cannabis goods are sold or displayed. This term requires a definition in order to differentiate it from other areas of the licensed premises. The proposed regulations impose specific rules that apply to the retail area. This definition allows a licensed retailer to clearly identify these areas within their facility.

Subsection (s) defines “sublet” as to lease or rent all or part of a leased or rented property. The proposed regulations do not allow a retail operator to sublet any portion of the licensed premises. In order to clarify what is meant by the term sublet, this definition is required. This definition was taken from the dictionary definition of the word sublet.

Subsection (t) defines “transport” as the physical movement of cannabis goods from one licensed premises to another licensed premises. This is necessary to distinguish between the transportation of cannabis goods which is between licensees and delivery of cannabis goods which is from a licensed retailer, nonprofit, or microbusiness engaged in retail to a customer. This definition is consistent with the use of transport in the Act.

Subsection (u) defines “vehicle alarm system” as a device or series of devices installed to discourage theft of the vehicle or its contents and is intended to summon general attention or to summon law enforcement as a result of an indication of an attempted breach of the commercial vehicle. The MAUCRSA requires the safe and secure transport and handling of cannabis goods. This definition clarifies and helps licensees to better understand the level of security that is required on their vehicles. The enumerated safety measures were selected based on their level of security, availability to the market and associated cost. The definitional type and kind of security measures are in-line with other jurisdictions regulating the sale and transport of medicinal cannabis goods.

§ 5001. Temporary License Application Requirements

Under Business and Professions Code section 26053, all commercial cannabis activity shall be conducted between licensees; which means that without a state issued license a commercial cannabis business would be unable to do business with other commercial cannabis businesses. In recognizing that many commercial cannabis businesses were already in operation for medicinal cannabis prior to January 1, 2018, the legislature created a temporary license with fewer requirements than an annual license so that licensing authorities could quickly process an application thereby allowing the businesses in operation to continue operations or allowing them to shut down for a very brief time while the application was processed. Business and Professions Code section 26050.1 provides that until January 1, 2019 a licensing authority may issue a temporary license if an applicant submits the following: 1) a written request to the licensing authority in a manner prescribed by the licensing authority; 2) a copy of a valid license, permit, or other authorization, issued by a local jurisdiction, that enables the applicant to conduct commercial cannabis activity at the location requested for the temporary license; and 3) the temporary license application fee, if any, required by the licensing authority.

The purpose of this proposed section is to prescribe the manner in which a written request for a temporary license is submitted to the Bureau. The proposed section would benefit the public by providing them with clear direction on how to apply for a license from the Bureau. Further this proposed section would benefit the public by requiring a limited number of items from applicants, so that the Bureau will be able to review these applications much faster than annual applications and quickly approve businesses that are currently in operation so that they do not have to shut their operations down while waiting for a license from the Bureau. This proposed section would also benefit the public at large by requiring that applicants provide enough documentation regarding their operations to the Bureau to determine that they are doing so in a manner that is consistent with preserving the health and safety of the public.

Proposed subsection (a) would clarify that applications for a temporary license may be completed and submitted online through the Bureau's website or by delivering a printed copy to the Bureau's office(s). This section is necessary to clarify where and how an application may be submitted to the Bureau. Permitting online submission provides flexibility for the applicant to submit the application from anywhere in the State. The State of California is very large and requiring an applicant to physically turn in hard copies in person in Sacramento would be tremendously burdensome on the applicant and the burgeoning industry. Permitting applicants to submit electronically also helps the Bureau process the applications in an effectively and timely fashion.

Proposed subsection (b) would specify that applicants that wish to apply online must first register for a user account by doing the following: 1) creating a user name, password, and security question and answer; 2) provide an email address; and 3) provide the owner's first and last name, primary phone number, social security number or individual taxpayer

identification number, date, and mailing address. These items are necessary to identify the applicant.

Proposed subsection (c) would clarify that an application must be completed by an owner and that an application must be submitted for each temporary license applied for. This proposed section is necessary to clarify the statutory requirements that an applicant be an owner (Bus. & Prof. Code § 26001(c)) and obtain a separate license for each location where it engages in commercial cannabis activity (Bus. & Prof. Code § 26053(d)).

Repeating the statutory requirements here is necessary for clarity and benefits applicants by placing the requirements in one section in the regulations rather than spread out in various statutory sections.

Proposed subsections (c)(1)-(c)(4) would specify that applicants provide the legal business name of the applicant, the email address of the applicant's business, a telephone number for the premises, the business' federal employer identification number, and a description of the business organizational structure. These items are necessary to identify the applicant and the applicant's business. These items are also necessary for verifying that the person listed on the local license, permit, or other authorization submitted with the application is the same as the person applying for the license. This information is also beneficial for verifying with local jurisdictions that applicants are in compliance with the local jurisdictions ordinances and regulations.

Proposed subsection (c)(5) would require the applicant to list the license type and license designation (A or M) for all license types except testing laboratories who do not receive such a designation under MAUCRSA. This information is necessary to issue the applicant the correct license and to ensure that the application contains everything necessary for that license type.

Proposed subsection (c)(6) would require an applicant to provide contact information for the applicant's designated primary contact person including the name, title, telephone number, and email address if applicable. This information is necessary so that the Bureau knows who to contact regarding questions or issues with an application or license.

Proposed subsection (c)(7) would require that each owner provide the owner's name, title, percentage of ownership, mailing address, telephone number, and email address if applicable. This information is necessary to identify the owners of a business. MAUCRSA requires that the owners of a commercial cannabis business be qualified for a license. Further, under Business and Professions Code section 26053(b), a person that holds a state testing laboratory license is prohibited from licensure for any other activity. The Bureau must be able to identify owners to ensure that an owner is not issued a testing laboratory license in addition to any other type of license.

Proposed subsection (c)(8) would require the applicant to provide the physical address of the premises to be licensed. This is necessary because under MAUCRSA a license may only be issued if both the applicant and the premises qualify for licensure. Further, the Bureau must know where the premises is located in order to do inspections and to verify

with the local jurisdiction that the applicant is authorized to engage in commercial cannabis activity at the premises.

Proposed subsection (c)(9) would require the applicant to provide evidence that the applicant has the legal right to occupy and use the proposed location. Business and Professions Code section 26051.5(a)(3) requires this information for an annual license. The Bureau determined that it was necessary to include this information with the temporary application to ensure that the landowner is aware that commercial cannabis activity is being conducted at the location and that the landowner approves of such activity. This reduces the risk of a landowner later stating that an applicant does not have the right to engage in commercial cannabis activity and evicting the licensee which could lead a licensee to divert commercial cannabis goods to the unlicensed market.

Proposed subsection (c)(10) would require an applicant to submit a premises diagram with their application. This is a requirement for the annual license under Business and Professions Code section 26051.5(c), however the Bureau determined it was also necessary for the temporary application. The diagram is necessary because the Bureau must know the layout of a premises in order to effectively carry out its duties under the Act. Requiring a premises diagram also allows applicants to receive feedback on their layout from the Bureau and adjust their layout prior to applying for the annual license.

Proposed subsection (c)(11) requires a copy of a valid license, permit, or other authorization issued by a local jurisdiction, that enables the applicant to conduct commercial cannabis activity at the location requested for the temporary license. Further, this proposed subsection would specify that “other authorization” means at a minimum a written statement or reference that clearly indicates the local jurisdiction intended to grant permission for the commercial cannabis activity or to the person to conduct commercial cannabis activity at the premises. Lastly, the proposed subsection would specify that the Bureau shall contact the applicable jurisdiction to confirm the validity of the authorization and if the jurisdiction does not respond within 10 calendar days, the Bureau shall consider the authorization valid. This proposed subsection is necessary to comport with the statutory requirement that a valid license, permit or other authorization be submitted for a temporary application and define what “other authorization” is as this is not defined in the Act. Lastly, the 10-day requirement is necessary because the Bureau determined 10 days was an adequate amount of time for a local jurisdiction to receive and confirm or deny an applicant’s authorization while still allowing the Bureau to complete the processing of the application in a short time frame.

Proposed subsection (c)(12) requires applicants to attest under the penalty of perjury that the information contained within and submitted with the application is complete, true, and accurate and that they understand that a misrepresentation of fact is cause for rejection of the application, denial of the license, or revocation of a license issued. This section is necessary to conform with requirements for the annual license. This also provides applicants with notice that any misrepresentations may lead to a license denial or

disciplinary action. In order for the Bureau to properly evaluate an application accurate information is critical.

Proposed subsections (d)-(g) are restatements of the provisions contained in Business and Professions Code section 26050.1 and are included here for clarity.

Proposed subsection (h) would specify that the Bureau shall not issue any temporary licenses or extensions after December 31, 2018. The purpose of this section is to clarify Business and Professions Code section 26050.1(c), which states that the section is repealed as of January 1, 2019. This section is necessary so that temporary licensees will know that after December 31, 2018, no temporary licenses will be issued and no further extensions of those licenses will be issued. It also clarifies the temporary licenses with expiration dates beyond 2018 cannot be extended beyond that expiration date. If temporary license holders do not understand that their temporary license will not be extended and that they must have their annual license prior to the expiration of their temporary license they could be faced with having to shut their business down while they wait for their annual license to be approved. Including this provision in the proposed regulation ensures that licensees are aware of the timeframe to acquire an annual license.

§ 5002. Annual License Application Requirements

In order to obtain a license an application must first be submitted to the Bureau. The purpose of this section is to specify what information must be provided by the applicant in the application. Business and Professions Code section 26051.5 enumerates specific, yet limited information an applicant is required to include in the application. Additionally, the Act places a limit on the licenses an owner of a testing laboratory may have therefore, the proposed regulation includes information that will be necessary in order for the Bureau to determine that an individual or entity is not obtaining licenses that the applicant is not eligible to have.

Proposed subsection (a) is necessary for application processing. Permitting online submission provides flexibility for the applicant to submit the application from anywhere in the State. The State of California is very large and requiring an applicant to physically turn in hard copies in person in Sacramento would be tremendously burdensome on the applicant and the burgeoning industry. Permitting applicants to submit electronically also helps the Bureau process the applications in an effectively and timely fashion.

Proposed subsection (b) would specify that applicants that wish to apply online must first register for a user account by doing the following: 1) creating a user name, password, and security question and answer; 2) provide an email address; and 3) provide the owner's first and last name, primary phone number, social security number or individual taxpayer identification number, date, and mailing address. These items are necessary to identify the applicant.

Proposed subsections (c)(1)—(c)(4) would specify that the applicant must provide the name of the applicant, the DBA of the applicant, the license type the applicant is applying for, and lastly must pay the application fee in proposed section 5014. These items are necessary to identify the applicant's legal business identity and the license that the

applicant is requesting as well as to clarify that payment of the application fee is necessary at the time the application is submitted.

Proposed subsections (c)(5) would allow an owner that is serving or has previously served in the military to disclose their service and receive expedited application processing if the owner can provide evidence of honorable discharge. This optional disclosure applies to all Department of Consumer Affairs boards and Bureaus, which includes the Bureau, through Business and Professions Code section 115.4 and is included here for clarity.

Proposed subsections (c)(6)—(c)(7) would require the applicant to the license types, license numbers, the date the license was issued, and which licensing authority issued the license for any licenses the applicant holds from the Bureau and all other state cannabis licensing authorities. The applicant would also be required to disclose whether the applicant has been denied a license or had one revoked or suspended by the Bureau or any other state cannabis licensing authority. These subsections are necessary to ensure that the granting of a license would not violate the provision in Business and Professions Code section 26053, subdivision (b) prohibiting a person that holds a state testing laboratory license from receiving any other type of cannabis license. It is also necessary for the Bureau to know if a license has ever been denied, revoked, or suspended as these could be grounds for denial of the application.

Proposed subsection (c)(8) would require the applicant to provide the physical address of the premises to be licensed and if the Bureau is unable to verify the address provided is valid, then the applicant shall provide a document that confirms the physical address of the premises. Suggested documents to meet this requirement are provided to give guidance to licensees. This is necessary because under MAUCRSA a license may only be issued if both the applicant and the premises qualify for licensure. Further the Bureau must know where the premises is located in order to do inspections and to verify with the local jurisdiction that the applicant is authorized to engage in commercial cannabis activity at the premises. The documentation is necessary to verify that the address provided by an applicant is a legal and accurate address for the premises.

Proposed subsection (c)(9)—(c)(12) would require specific contact information for the commercial cannabis business including the mailing address, the telephone number for the premises, the website address, the email address, and the federal employer identification number. These items are necessary to contact the premises. Further, they are necessary for monitoring the commercial cannabis business once it is licensed to ensure the business is complying with laws and regulations.

Proposed subsection (c)(13) would require an applicant to provide contact information for the applicant's designated primary contact person including the name, title, telephone number, and email address if applicable. This information is necessary so that the Bureau knows who to contact regarding questions or issues with an application or license.

Proposed subsections (c)(14)—(c)(19) would require the applicant to provide the business organizational structure, the business-formation documents, a list of all fictitious business names the applicant is operating under, the certificate of qualification if the applicant is a foreign corporation, financial information, and, as required by Business and Professions Code section 26051.5(d), a list of every individual who has a financial interest. This information is necessary to determine how the commercial cannabis business will be

organized and to ensure that all owners as defined in proposed section 5003 and all financial interest holders in proposed section 5004 are identified.

In order for the Bureau to conduct a thorough and effective evaluation of an applicant's submission, to ensure the applicant is a bona fide and qualified applicant under the law, the Bureau must receive specific information from the applicant. The requirements contained in proposed subsections (c)(20)(A)–(c)(20)(K) are necessary for the Bureau to accurately determine and verify the true identity of individual owners as defined in proposed section 5004.

Under Business and Professions Code sections 144 and 26051.5 (a)(1) the Bureau is required to request and conduct criminal history record checks on all applicants. The information contained in proposed subsection (c)(20)(L)(i) – (vi) clarifies what information is needed by the Bureau in order to gather all pertinent criminal history information in order to properly conduct the statutorily mandated checks. The information requested is necessary to determine the facts and circumstances of the conviction to determine if it is substantially related to the licensed activity, and to determine if the owner has been rehabilitated. This information could lead to a license denial.

Proposed subsection (c)(20)(M) requires the applicant to provide information about any administrative order or civil judgment for labor standards violations, any suspension or revocation of a commercial cannabis license, or sanctions for unlicensed commercial cannabis activity taken against the applicant or a business entity in which the applicant was an owner or officer within the three years immediately preceding the date of the application. This information is necessary to inform the Bureau of all pertinent information that could be grounds for denial of the application.

Proposed subsection (c)(20)(N) requires the applicant to attest that the information is true. Business and Professions Code Section 26051.5 requires that any applicant for a license from the Bureau provide this type of attestation.

Proposed subsection (c)(21) would require the applicant to provide evidence that the applicant has the legal right to occupy and use the proposed location as required by Business and Professions Code section 26051.5(a)(3). This requirement is included here for clarity and is necessary so that applicants may have all the requirements for an application listed in one section.

Proposed subsection (c)(22) would require, pursuant to Business and Professions Code section 26051.5, subdivision (a)(3), that the applicant provide evidence that the proposed premises is in compliance with subdivision (b) of Section 26054, which requires that a premises shall not be within a 600-foot radius of a school providing instruction in kindergarten or any grades 1-12 or other enumerated facility for the care of children, unless the licensing authority or local jurisdiction specifies a different radius. This requirement is included here for clarity and so that applicants may have all the requirements for an application listed in one section.

Proposed subsection (c)(23) would require that an applicant with 20 or more employees attest that the applicant has entered into a labor peace agreement and will abide by the terms of the agreement or, if they have not yet entered into such an agreement, then provide a notarized statement that the applicant will enter into and abide by the terms of a labor

peace agreement as soon as reasonable practicable after licensure. This subsection is necessary to fulfill the statutory requirements of Business and Professions Code section 26051.5(a)(5). This clarification is necessary because it highlights the importance of a labor peace agreement for applicants that have never dealt with labor issues. The subsection also requires a copy of the page of the labor peace agreement containing the signatures as evidence of the agreement. Further, it protects the employees of the applicant by ensuring that once licensed the licensee does not forgo or put off its responsibility to enter into such an agreement.

Proposed subsection (c)(24) would repeat the requirement of Business and Professions Code section 26051.5(a)(6) that an applicant provide a valid seller's permit number or, if it has not yet received one, indicate that the applicant is currently applying for the seller's permit. This requirement is included here and is necessary to provide clarity so that applicants may have all the requirements for an application listed in one section.

Proposed subsection (c)(25) would require a premises diagram be submitted with the application pursuant to Business and Professions Code section 26051.5 (c). This is necessary because it is required under the Act and without a detailed, thorough and legible description of the proposed premises, the Bureau is unable to ensure the proposed premises meets all statutory limitations and requirements for the proposed activity.

Proposed subsection (c)(26) would require proof of a bond. This is necessary because it is required by the Act under Business and Professions Code section 26051.5(a)(10) and is repeated here for clarity and so that applicants may have all the requirements for an application listed in one section.

Proposed subsection (c)(27) would require that testing laboratory applicants provide the certificate(s) of accreditation that is required by proposed section 5702, which is also required under Business and Professions Code section 26100(g), or the information required by proposed section 5703. These requirements are repeated in the application for clarity so that applicants may have all the requirements for an application listed in one section.

Business and Professions Code section 26055, subdivision (d) licensing authorities may not approve an application that would violate the provisions of any local ordinance or regulation adopted in accordance with Section 26200. Further, Business and Professions Code section 26055(e), provides that an applicant may voluntarily provide proof of a license, permit, or other authorization from the local jurisdiction verifying that the applicant is in compliance with the local jurisdiction and an applicant that provides such proof shall be presumed in compliance unless the licensing authority is notified otherwise by the local jurisdiction. Proposed subsection (c)(28) clarifies the Bureau's process for notifying local jurisdictions of the application and provides that if the local jurisdiction does not respond within 10 calendar days, the Bureau shall consider the authorization valid. In order to encourage applicants to get licensed and comply with the Bureau's regulations and stay out of the illegal market, the Bureau must be able to process the applications quickly. Providing 10 calendar days was determined by the Bureau to be a sufficient amount of time for the local jurisdiction to review its records and respond and is not too long of a time for the processing of the application to be delayed while waiting for a response from the local jurisdiction.

Business and Professions Code Section 26051.5(b) requires that applicants for licensure include in their application a detailed description of the applicant's operating procedures for cultivation, extraction and infusion methods, transportation, inventory procedures, quality control procedures, and security protocols. Section 26051.5 does not specify what information is required to be included in the operating procedures included with the application. The Bureau has developed forms and incorporated them by reference in order to specify what information is required to be submitted to the Bureau to describe the applicant's inventory procedures. The purpose of collecting this information is to allow the Bureau to make an informed determination on whether the applicant's planned operations will comply with the various requirements prior to issuing a license.

Proposed subsection (c)(29) would require licensees to use forms for submitting their operating procedures. All of the forms would require the applicant to provide the business name, the application type, and the primary contact name, email, and phone. This is necessary to identify which application the procedures are for. Often applicants email certain documents rather than uploading them to the online licensing system. With this information, the Bureau will be able to identify the appropriate application to attach the procedures too.

Proposed subsection (c)(29)(A) would require applicants use Form BCC-LIC-015 (New 7/18) for their transportation procedures. Proposed item 1 on Form BCC-LIC-015 would require the applicant to identify whether the applicant intends to transport cannabis goods, or will be contracting for transportation services. This is necessary to ensure that an applicant that intends to transport cannabis goods has applied for a license that would allow them to engage in transport. This is also necessary to ensure that an applicant that will be contracting for transportation services is aware that they must have a licensee that is approved for transportation transporting their goods.

Proposed items 2a and 2b on Form BCC-LIC-015 would require the applicant to specify the license types the applicant intends to transport between and the geographic regions the applicant will be transporting to and whether the applicant expects to transport overnight. This is necessary because distributor transport only licensees are only allowed to transport live plants and seeds from a nursery to a retailer and they cannot transport other cannabis goods to retailers. Knowing which license types the applicant is intending to transport between will allow the Bureau to ensure that the applicant is aware of any and all restrictions placed on the license type they are applying for and then allows the licensee to correct the application if they have selected the wrong license type for their planned operation. Knowing the geographic region and whether the applicant intends to stay overnight is necessary because vehicles containing cannabis goods cannot be left in a residential area overnight. Having this information with the application will allow the Bureau to review where the applicant intends to go and ensure that the applicant is aware of the restrictions on leaving the vehicle overnight and has planned accordingly.

Proposed items 2ci-2civ on Form BCC-LIC-015 requires the applicant to provide specific information about the vehicles and trailers that will be used. This includes: 1) the number

of vehicles, 2) the type of vehicles or trailers, including make, model, and VIN, 3) registration and insurance information, and 4) whether the applicant will be applying for a motor carrier permit. This is necessary so that the Bureau can ensure that the applicant is complying with the requirement that the applicant lawfully possesses the vehicles either through ownership or a valid lease. This is also necessary for the Bureau to confirm to law enforcement that a vehicle being used for transport is approved for such transport by the Bureau in cases where a vehicle is stopped or inspected by law enforcement. The motor carrier permit is required by the MAUCRSA for any vehicle transporting goods for hire. Requiring this information on the form ensures that the applicant is made aware of the requirement and for the Bureau to ensure that the applicant is going to comply with the requirement.

Proposed items 2di-ii on Form BCC-LIC-015 requires specific information about the employees that will be transporting the goods as either a driver or passenger and whether security personnel will be transporting the cannabis goods. This is necessary because only employees of the licensee or security personnel that are at least 21 years of age can be in a vehicle transporting cannabis goods pursuant to the proposed regulations. This ensures that applicants are aware of the requirements and will be complying with them.

Proposed item 2e on Form BCC-LIC-015 requires specific information regarding the storage of cannabis goods in the vehicle, including what area of the vehicle will be used, how the goods will be secured, and how the applicant will ensure the cannabis goods are not visible or identifiable from the outside of the vehicle. This is necessary to ensure that the applicant is aware of the proposed regulatory requirements for the transport of cannabis goods and that they will be complying with the requirements.

Proposed item 2f requires on Form BCC-LIC-015 information regarding all security measures the applicant will be using. This is necessary because the proposed regulations require that any vehicle transporting cannabis goods have an alarm system. This ensures that applicants are aware of the requirement and will be complying with it. It also allows the Bureau to determine whether the applicant's planned operation will be adequate to ensure the health and safety of the public by having adequate security measures to protect the cannabis goods from theft.

Proposed item 2g on Form BCC-LIC-015 requires the applicant to inform the Bureau if they are located on the same parcel of land or within the same building of other licensees they will be transporting to using alternative means because of the impracticability/impossibility of using a vehicle. This ensures that applicants are aware of the requirements for transporting cannabis goods in another manner than with a vehicle and ensures that they will be complying with the requirements.

Proposed item 3 on Form BCC-LIC-015 would require the applicant to provide a list of transportation services they will be contracting with, if applicable, and any contract. This is necessary for the Bureau to ensure that the applicant is contracting with licensed distributors and not intending to engage an unlicensed transport company.

Proposed subsection (c)(29)(B) would require applicants use Form BCC-LIC-016 (New 7/18) to provide their inventory procedures. The form requires the applicant to provide information regarding their practices for keeping their inventory of cannabis goods. All the information requested in the proposed form would allow the Bureau to get a better understanding of the details of the applicant's planned inventory procedures. This will allow the Bureau to better assess the likelihood that the applicant will comply with all requirements and allow the Bureau to be better able to determine whether the applicant is fit for licensure.

Proposed item 1 on Form BCC-LIC-016 requires the applicant to identify, using a diagram, where their inventory of cannabis goods will be held. This information would allow the Bureau to determine whether the applicant plans to keep the cannabis goods in a location that is properly secured are required by the regulations. By ensuring that the cannabis goods are held in a secure location, the risk of theft or other loss is reduced.

Proposed item 2 on Form BCC-LIC-016 requires the applicant to describe who has access to the areas in which cannabis goods are stored. This information would allow the Bureau to determine whether access to the inventory of cannabis goods is limited to only those who legitimately require access. By ensuring that only individuals who require access to the cannabis goods are the only ones who may access the goods, the risk of theft or other loss may be reduced.

Proposed item 3 on Form BCC-LIC-016 requires the applicant to describe the security measures in place at the location where the cannabis goods are stored. This information would allow the Bureau to properly assess whether the applicant's planned security measures are compliant with the requirements in the regulations and whether they are likely to be effective in securing the cannabis goods. Ensuring that the applicant has effective security measures that comply with the Bureau's regulations will reduce the risk of theft or other loss by limiting the risk of unauthorized individuals accessing the cannabis goods.

Proposed item 4 on Form BCC-LIC-016 requires the applicant to describe the conditions of the location where the cannabis goods will be held. This includes information on whether the temperature and the humidity in the location can be controlled. This information would allow the Bureau to assess whether the conditions of the location where cannabis goods will be held are likely to be effective in maintaining the quality of the cannabis goods and reducing the risk of degradation or contamination. It is vital that the quality of the cannabis good be maintained and that the cannabis goods be safe from any risk of contamination. Therefore, it is important for the Bureau to assess whether the applicant's planned operations are likely to achieve this goal.

Proposed item 5 on Form BCC-LIC-016 requires the applicant to describe the training provided to employees regarding inventory procedures. This information would allow the Bureau to effectively assess whether the applicant's employees will be aware of the

inventory requirements in the Bureau's regulations and whether the employees are likely to take steps to ensure that the requirements are met. By ensuring that the applicant's employees are properly trained in inventory procedures, the Bureau can reduce the risk of theft or other loss, as well as reduce the risk of degradation or contamination to the cannabis goods.

Proposed item 6 on Form BCC-LIC-016 requires the applicant to describe the process for receiving new inventory of cannabis goods. This information is important for the Bureau to be able to assess whether the applicant is likely to comply with regulatory requirements for the intake of cannabis goods.

Proposed item 6a on Form BCC-LIC-016 requires the applicant to describe where the cannabis goods are received. This information allows the Bureau to properly assess whether the intake area is properly secure and free of things that may increase the risk of theft, loss, degradation, or contamination.

Proposed item 6b on Form BCC-LIC-016 requires the applicant to identify who is to receive cannabis goods into the applicant's inventory. This information would allow the Bureau to determine whether access to the inventory of cannabis goods is limited to only those who legitimately require access. By ensuring that only individuals who require access to the cannabis goods are the only ones who may access the goods, the risk of theft or other loss may be reduced.

Proposed item 6c on Form BCC-LIC-016 requires the applicant to describe how the cannabis goods are moved to the inventory storage area. This information would allow the Bureau to properly assess whether the applicant's practices for moving inventory comply with the requirements in the regulations.

Proposed item 6d on Form BCC-LIC-016 requires applicants to describe the records that are produced when new inventory is accepted. This information allows the Bureau to ability to properly assess whether the applicant is properly documenting their commercial cannabis activates. Proper documentation is important because proper documentation allows to Bureau the ability to verify that all requirements are being followed and that there has not been and diversion of cannabis goods. Additionally, good record keeping allows the Bureau to easily investigate a situation if the need arises.

Proposed item 7 on Form BCC-LIC-016 requires applicants to describe the records that are produced in the tracking of inventory. This information allows the Bureau to ability to properly assess whether the applicant is properly documenting their commercial cannabis activates. Proper documentation is important because proper documentation allows to Bureau the ability to verify that all requirements are being followed and that there has not been and diversion of cannabis goods. Additionally, good record keeping allows the Bureau to easily investigate a situation if the need arises.

Proposed item 8 on Form BCC-LIC-016 requires the applicant to describe the process for removing cannabis goods from inventory. This information is important for the Bureau to be able to assess whether the applicant is likely to comply with regulatory requirements for the removal of cannabis goods from inventory.

Proposed item 8a on Form BCC-LIC-016 requires the applicant to describe what happens to cannabis goods that are removed from inventory, including any records that are produced. This information allows the Bureau to ability to properly assess whether the cannabis goods are properly handled and sent only to persons and locations where they are allowed to be sent under the regulations and whether the applicant is properly documenting their commercial cannabis activates. Proper documentation is important because proper documentation allows to Bureau the ability to verify that all requirements are being followed and that there has not been and diversion of cannabis goods. Additionally, good record keeping allows the Bureau to easily investigate a situation if the need arises.

Proposed item 9 on Form BCC-LIC-016 requires the applicant to describe the methods used to ensure that the cannabis goods stored do not degrade. This information would allow the Bureau to assess whether the applicant's planned operations are likely to be effective in maintaining the quality of the cannabis goods and reducing the risk of degradation or contamination. It is vital that the quality of the cannabis good be maintained and that the cannabis goods be safe from any risk of contamination. Therefore, it is important for the Bureau to assess whether the applicant's planned operations are likely to achieve this goal.

Proposed item 10 on Form BCC-LIC-016 requires applicants to describe how often inventory reconciliation is conducted. This information is required in order for the Bureau to verify whether the applicant will meet the minimum requirements for conducting inventory reconciliation. Regular inventory reconciliation allows the applicant and the Bureau to determine whether the applicant's inventory record keeping system is effective. Additionally, regular inventory reconciliation allows for the discovery of the loss of cannabis goods.

Proposed item 10a on Form BCC-LIC-016 requires the applicant to describe the process for inventory reconciliation and the types of records that are produced. This information allows the Bureau to assess whether the applicant's plans methods of inventory reconciliation are likely to be effective in reducing the risk of loss and allowing for the discovery of a loss of cannabis goods.

Proposed subsection (c)(20)(C) would require applicants use Form BCC-LIC-017 (New 7/18) to provide the Bureau with their non-laboratory quality control procedures. The proposed form requires applicants to provide information regarding the applicant's packaging and labeling procedures, including procedures for verifying that the cannabis goods have all the proper labels. The applicant is also required to provide information

pertaining to the applicant procedures for preventing the deterioration or contamination of cannabis goods held by the licensee, the procedure for handling returns.

For distributor applicants proposed item 4 requires the applicant to provide the processes for storage, packaging, labeling, and sampling as well as where on the licensed premises these activities will occur. Finally, the propose form requires the applicant to provide information regarding the procedure for handing cannabis goods that have passed testing and cannabis goods that have failed testing.

All the information requested in the proposed form would allow the Bureau to get a better understanding of the details of the applicant's planned quality control procedures. This will allow the Bureau to better assess the likelihood that the applicant will comply with all requirements. This in turn, will allow the Bureau to be better able to determine whether the applicant is fit for licensure.

Proposed subsection (c)(29)(D) would require applicants to use Form BCC-LIC-018 (New 7/18) to provide their security procedures to the Bureau. The proposed security procedures form identifies certain security information that applicants must provide in support of an application for licensure. Specifically, the form requires applicants to: (1) describe who is responsible for implementing the security operating procedures; (2) describe how the applicant will ensure all access points will be secured; (3) describe the applicants procedures for allowing individuals access to the premises; (4) describe how the applicant will adhere with employee badge requirements; (5) provide a description of the video surveillance system; (6) provide information regarding the use of security personnel onsite; and (7) provide a description of the onsite security alarm system.

The purpose of this form is to specify what information must be provided by the applicant with regards to its security practices. Specifically, this form provides the Bureau a mechanism to collect information that is necessary for the Bureau to evaluate whether applicants can comply with the proposed minimum-security provisions enumerated in sections 5042 through 5047 of the proposed regulations. This form also enables the Bureau to consider, whether an applicant's proposed security measures are appropriate for the premises location and type of license. This form will also reduce potential misunderstandings regarding the relevant security information that licensees must disclose to the Bureau for review.

Proposed item (1) on Form BCC-LIC-018 requires the applicant to describe the person responsible for implementing the security operating procedures. This is necessary to help ensure that the security operating procedures will be implemented and carried out. This will also help to eliminate any confusion on the part of the licensee as to who within their business may be responsible for the security operating procedures, because confusion or misunderstanding as to the person responsible may lead to certain security measures being missed. Failure to comply with required security measures places the licensees and the public at risk.

Proposed item (2) on Form BCC-LIC-018 requires the applicant to describe how they will ensure all access points will be secured, which includes a description of entrances and exits, windows, and doorways, and the types of locks used. This is necessary to ensure that the applicant has secured all access points in the appropriate manner. The proposed regulations specify certain requirements for access points, such as requiring commercial grade locks for limited access areas and all points of entry and exit.

Proposed item (3) on Form BCC-LIC-018 specifies the information that the applicant must provide regarding the applicant's procedures for allowing individuals access to the premises. This information is necessary to enable the Bureau to evaluate whether the applicant's proposed procedures sufficiently restrict access to authorized personnel, assign appropriate roles responsibilities to personnel, and document the on-site presence of non-employee authorized individuals.

Proposed item (3)(a) on Form BCC-LIC-018 requires the applicant to provide a list of employees who have access and their respective roles and responsibilities. This is necessary to determine who will have access to the premises, so as to ensure there is no unauthorized access of licensed premises, which could lead to increased risk of illegal diversion of cannabis goods, or other exposure to criminal activity or security breaches.

Proposed item (3)(b) on Form BCC-LIC-018 requires the applicant to describe how the applicant will ensure that access to the premises is controlled such that only authorized persons can access the premises and limited-access areas. This is necessary to ensure that only authorized persons will have access to the licensed premises and cannabis goods stored on the licensed premises. Unauthorized access or exposure to cannabis goods increases the risk of illegal diversion of cannabis goods.

Proposed item (3)(c) on Form BCC-LIC-018 requires the applicant to describe the applicant's procedure for accurately documenting the on-site presence of non-employee authorized personnel. This is necessary for the applicant to maintain an accurate record of non-employees authorized to be onsite, so as to ensure there is no unauthorized access of licensed premises, which could lead to increased risk of illegal diversion of cannabis goods, or other exposure to criminal activity or security breaches. This will also help the applicant comply with the requirement to maintain accurate records.

Proposed item (4) on Form BCC-LIC-018 describe how the applicant will adhere with employee badge requirements, as required under proposed regulations section 5043. This is necessary to ensure that the employee badge is meeting all requirements, such as proper photo identification and other information required on the employee badge.

Proposed item (5) on Form BCC-LIC-018 requires the applicant to describe the video surveillance system that will be used at the proposed premises. This is necessary to ensure that the video surveillance system meets all requirements, and is fit for its intended use.

Proposed item (5)(a) on Form BCC-LIC-018 requires the applicant to describe the types of camera and video storage equipment that the applicant will use at the proposed premises. This is necessary to ensure that the requirements for camera and video storage are met, to

maintain the integrity of the video so as to be useful in corrective action plans, as well as to determine any criminal activity.

Proposed item (5)(b) on Form BCC-LIC-018 requires the applicant to describe the placement of the cameras and the number of cameras to be used. This is necessary to ensure that the applicant has submitted a comprehensive premises diagram, which requirements camera placement, and that the cameras are appropriately and correctly placed, to deter criminal activity or diversion of cannabis goods.

Proposed item (5)(c) on Form BCC-LIC-018 requires the applicant to describe the applicant's procedures for maintaining the onsite video surveillance equipment. This is necessary to ensure that the applicant maintains such equipment to preserve the integrity and quality of the camera and video.

Proposed item (5)(d) and (5)(e) on Form BCC-LIC-018 requires the applicant to describe how the applicant will be notified if the surveillance system fails and to describe how the surveillance system will be monitored. This is necessary to ensure that the applicant is properly notified of any system failures, so that they can be immediately corrected. The surveillance system is essential in ensuring a safe and secure premises, so continued operation is important.

Proposed item (5)(f) on Form BCC-LIC-018 requires the applicant to describe how the applicant will immediately produce copies of video recordings at the licensed premises upon request of the Bureau. This is necessary to ensure that the Bureau or law enforcement has the ability to review video recordings that have been preserved and not exposed to unauthorized access or tampering.

Proposed item (5)(g) on Form BCC-LIC-018 requires the applicant to describe how the applicant will share the video surveillance system with other licensees, when shared services are being used for the same location. This is necessary to ensure that there is a comprehensive system and procedures in place for the sharing of a video surveillance system so that applicants sharing the system are aware of their respective duties and responsibilities in the use and monitor of the video surveillance system. This is also important because applicants sharing a video surveillance system are each liable for the other's misuse or failure to comply with the video surveillance requirements.

Proposed item (6) on Form BCC-LIC-018 specifies the information that the applicant must provide regarding the use of security personnel onsite. This information includes whether the security personnel are contracted or employed by the applicant, where the personnel will be stationed and the areas being covered, hours of personnel, whether the personnel will also serve other licensees, and whether the personnel will be armed. This is necessary to ensure that the applicant is meeting the security personnel requirements. This will also help the applicant ensure that security personnel are properly utilized and effective in ensuring a safe and secure premises.

Proposed items (6)(a) and (6)(d) on Form BCC-LIC-018 requires the applicant to notify the Bureau of whether the onsite security personnel are employed by the applicant or serving under contract from another entity and to describe how the applicant, if at all, will share

services provided by the security personnel with other licensees operating at the same location. This information is necessary for the Bureau to identify and communicate with the parties involved and affected in the event of a security breach or concern.

Proposed items (6)(b), (6)(c), and (6)(e) on Form BCC-LIC-018 requires the applicant identify where the security personnel will be primary found and the areas covered by roving security personnel, provide the hours during which an onsite security personnel will be at the proposed premises, and provide information on whether the security personnel will be armed while onsite. This is necessary for the Bureau to determine the scope of security services provided for at the proposed premises and determine if they are adequate.

Proposed item (7) on Form BCC-LIC-018 specifies the information that the applicant must provide regarding the onsite security alarm system that will be used. This is necessary to ensure that the applicant meets the requirements for the security alarm system, which is effective in ensuring a safe and secure premises.

Proposed item (7)(a) on Form BCC-LIC-018 requires the applicant to provide identifying and contact information or the person and entities that installed and who maintains the alarm system. This is necessary for the Bureau to verify that the installation and maintenance is provided by a qualified person.

Proposed items (7)(b) and (7)(d) on Form BCC-LIC-018 requires the applicant to describe the applicant's procedures for ensuring that the alarm system remains operational and how the applicant will be notified in the event of an alarm system malfunction. This information is necessary for the Bureau to evaluate whether the applicant is adequately prepared to maintain the functionality of the security system throughout the duration of the prospective licensure. This is also helpful to ensure that the security system is properly maintained.

Proposed item (7)(c) on Form BCC-LIC-018 requires the applicant to describe the alarm system features. This is necessary for the Bureau to determine whether the system is sufficiently capable of detecting potential security problems and meets the requirements for the security alarm system. This is also helpful to ensure that the applicant is well-versed in the use of the security alarm system, and that it is being properly used.

Proposed item 7(e) requires the applicant to describe how the applicant will share the security alarm system with other licensees, when shared services are being used for the same location. This is necessary to ensure that there is a comprehensive system and procedures in place for the sharing of a security alarm system so that applicants sharing the system are aware of their respective duties and responsibilities in the use and monitor of the security alarm system. This is also important because applicants sharing a security alarm system are each liable for the other's misuse or failure to comply with the security alarm requirements.

Proposed subsection (c)(29)(E) would require applicants to use Form BCC-LIC-019 (New 7/18) for their cannabis waste management procedures. This form provides the Bureau a mechanism to collect the information that is necessary for the Bureau to evaluate whether applicants can comply with the proposed waste handling provisions enumerated in sections 5054 and 5055 of the proposed regulations. Different licensees will have varying waste

generation levels and handling requirements; this form will enable the Bureau to evaluate whether the applicant's waste handling procedures are appropriate for the types of commercial cannabis activities requested.

The proposed form would require applicants to provide the business name and application type, as well as the applicant's primary contact name, email, and phone number. This information is necessary to identify which application the cannabis waste procedures are for. Often, applicants will email or drop-off certain documents, rather than uploading them to the online licensing system. Collecting this information as part of the form will enable the Bureau to identify the appropriate application to attach the non-laboratory quality control procedures too.

Proposed item 1 on Form BCC-LIC-019 would require the applicant to describe how cannabis waste is generated, stored, and managed within the licensed premises. This is necessary because the information collected as part of this item will give the Bureau a general overview of how cannabis waste is to be handled on the licensed premises. The information collected as part of this item will also allow the Bureau to determine whether cannabis goods are properly disposed of as cannabis waste, and are not accessible by unauthorized individuals or children.

Proposed item 2 on Form BCC-LIC-019 would require the applicant to identify the type of solid waste facility to which cannabis waste is transported from the premises. Not all licensees will dispose their cannabis waste onsite; many will require the waste they generate to be hauled to a licensed facility. This section is necessary because it enables the Bureau to determine whether applicants will comply with the waste management laws under Division 30 of the Public Resources Code.

Proposed item 3 on Form BCC-LIC-019 would require the applicant to describe their procedures for ensuring that cannabis waste is stored in a secured waste receptacle. Improper disposal of cannabis waste may inadvertently result in the diversion or access of cannabis waste by unauthorized individuals or children. The information collected as part of this item ensures that the Bureau is able to determine that applicants have procedures in place to ensure that cannabis goods are properly disposed of as cannabis waste and are inaccessible to unauthorized persons.

Proposed items 4 and 5 on Form BCC-LIC-019 would require the applicant who uses a third-party waste hauler to identify the type or types of third-party waste hauler(s) used and their process for documenting and confirming the receipt of cannabis waste at the solid waste facility. Certain entities are sanctioned to handle waste under Division 30 of the Public Resources Code. Moreover, improper disposal of cannabis waste may inadvertently result in the diversion or access of cannabis waste by unauthorized individuals or children. The information collected as part of this item is necessary for the Bureau to assure that waste generated by prospective licensees is handled and disposed of by the appropriate parties identified in existing waste management laws under the Public Resources Code and that there are appropriate procedures in place to adequately document the disposal of cannabis waste by the appropriate parties.

Proposed item 6 on Form BCC-LIC-019 would require self-hauling applicants to describe their procedures, including how the delivery is documented. Licensees have the option of hauling their own waste to a waste facility. The information collected as part of this item is necessary for the Bureau to determine whether applicants have procedures in place to assure the safe transport of cannabis waste to appropriate facilities. Moreover, the information collected as part of this item is necessary for the Bureau to confirm that applicants have procedures in place to adequately document the disposal of waste through certified weight tickets or other means.

Proposed items 7 and 8 on Form BCC-LIC-019 would require the applicant to identify whether the proposed commercial cannabis activities will result in the generation of hazardous waste and how such waste will be stored and managed within the licensed premises. Certain licensees, such as microbusinesses conducting manufacturing activities, may conduct activities that will result in the generation of hazardous waste, such as spent solvents or compressed gas cylinders. The information collected as part of this item is necessary for the Bureau to assure that applicants for licensure have procedures in place to handle such hazardous waste. The information collected as part of this item will also inform the Bureau, and its enforcement staff, of potential for exposure to such substances.

Proposed item 9 on Form BCC-LIC-019 would require applicants who intend to compost to describe their composting procedures. Section 5055 of the proposed regulations require licensees to conduct their composting activities in conformance with California Code of Regulations, title 14, chapter 3.1 (commencing with section 17850). The information collected as part of this item ensures that the Bureau is able to confirm that applicants are conducting composting activities in compliance with all relevant laws and regulations.

Proposed item 10 on Form BCC-LIC-019 would require applicants to identify whether their business will generate four or more cubic yards per week and how they intend on dealing with such waste. Some licensees may generate high levels of waste. The information collected as part of this item will ensure that the Bureau can confirm that applicants have procedures in place to adequately handle the waste generated at their licensed premises.

Proposed subsection (c)(29)(F) would require applicants to use Form BCC-LIC-020 (New 7/18) to provide to the Bureau their delivery procedures. The form requires applicants to provide information regarding the vehicles, personnel, documentation, and methods the applicant plans to use in conducting deliveries of cannabis goods. All the information requested in the proposed form would allow the Bureau to get a better understanding of the details of the applicant's planned delivery operation. This will allow the Bureau to better assess the likelihood that the applicant will comply with all requirements and will allow the Bureau to be better able to determine whether the applicant is fit for licensure.

Proposed item 1 on Form BCC-LIC-020 requires applicants to provide identifying information for each vehicle that will be used for delivery. This information includes the year, make, model, color, VIN, and license plate number. The applicant is also required to indicate whether the vehicle is equipped with a vehicle alarm system. This information will

allow the Bureau to effectively identify the vehicles that the applicant will be using to conduct deliveries. This will allow the bureau to assess whether the vehicles are compliant with the regulations. This would also provide the Bureau with a record of all the vehicles that have been authorized to be used for the delivery of cannabis goods. This would enable the Bureau the ability to easily identify when a vehicle has not been authorized for this use.

Proposed item 2 on Form BCC-LIC-020 requires the applicant to provide the name, date of birth, and driver's license for each employee that will be engaging in the delivery of cannabis goods. This information would allow the Bureau to verify that the delivery employees are legally authorized to operate a motor vehicle and are of an appropriate age to be conducting cannabis deliveries. Additionally, this would provide the Bureau with a record of all the employees who have been authorized to engage in delivery. This would allow the Bureau to easily determine when an individual has not been authorized to engage in delivery.

Proposed item 3 on Form BCC-LIC-020 requires the applicant to describe the training provided to employees regarding delivery procedures. This information would allow the Bureau to effectively assess whether the applicant's employees will be aware of the requirements in the Bureau's regulations and whether the employees are likely to take steps to ensure that the requirements are met. By ensuring that the applicant's employees are properly trained in delivery procedures, the Bureau can reduce the risk of theft or other loss, as well as reduce the risk of non-compliance.

Proposed item 4 on Form BCC-LIC-020 requires applicants to describe the process for accepting new delivery orders, including whether the applicant will a technology platform, how orders are received, and who receives the orders. This information is important for the Bureau to be able to assess whether the applicant is likely to comply with regulatory requirements for the intake of delivery orders.

Proposed item 5 on Form BCC-LIC-020 requires the applicant to describe the process for preparing orders of cannabis goods for delivery. This information would allow the Bureau to assess whether the applicant is likely to comply with all the requirements regarding the preparation of orders of cannabis goods for delivery. It is important for the Bureau to assess whether the applicant's planned process for preparing order is likely to lead to a risk of loss of cannabis goods.

Proposed item 6 on Form BCC-LIC-020 requires the applicant to describe how cannabis goods will be stored in the delivery vehicle, including the amount of cannabis goods that will be carried by the delivery employee. The Bureau's regulations have specific requirements for how cannabis goods must be stored in a delivery vehicle as well as how much cannabis goods a delivery employee may carry. This information would allow the Bureau to properly assess whether the applicant's plant delivery process is compliant with those requirements.

Proposed item 7 on Form BCC-LIC-020 requires the applicant to describe the process that a delivery employee goes through prior to leaving the licensed premises to conduct deliveries. This information allows the Bureau to assess whether this process is likely to comply with the regulatory requirements as well as whether the proper documentation is occurring to reduce the risk of theft or other loss at this stage.

Proposed item 8 on Form BCC-LIC-020 requires the applicant to describe the process for tracking the location of delivery employees who are conducting deliveries. The Bureau's regulations have specific requirements for how a licensee must track their delivery employees. This information would allow the Bureau to determine whether the applicant's planned operations comply with these requirements.

Proposed item 9 on Form BCC-LIC-020 requires the applicant to describe the methods used for communicating with delivery employees. It is important that licensees be able to communicate with delivery employees to ensure compliance with the various delivery requirements. This information would allow the Bureau to assess whether the applicant will be able to effectively communicate with delivery employees.

Proposed item 10 on Form BCC-LIC-020 requires the applicant to provide the methods of route guidance used by delivery employees. The Bureau's regulations require that delivery employees not deviate from the delivery route except for necessary stops. This information would allow the Bureau to assess whether the applicant's delivery employees will be able to effectively comply with that requirement.

Proposed item 11 on Form BCC-LIC-020 requires the applicant to describe the applicant's policy for delivery employees taking breaks and making stops while conducting deliveries. The Bureau's regulations require that delivery employees not deviate from the delivery route except for necessary stops. This information would allow the Bureau to assess whether the applicant's delivery employees will be able to effectively comply with that requirement. Additionally, the Bureau's regulations prohibit delivery employees from consuming cannabis goods while conducting deliveries. This information would allow the Bureau to determine whether the applicant's policies are consistent with this requirement.

Proposed item 12 on Form BCC-LIC-020 requires the applicant to indicate whether delivery employees are able to accept new orders for deliveries while conducting deliveries. The proposed item also requires applicants to describe this process if it is occurring. Although delivery employees are authorized to engage in the delivery of cannabis goods, delivery employees are not authorized to engage in the mobile sale of cannabis goods. This information will allow the Bureau to assess whether the applicant is following all requirements in accepting new delivery orders.

Proposed item 13 on Form BCC-LIC-020 requires the applicant to describe the process for preparing the delivery request receipt. The delivery request receipt is required by Business

and Professions Code Section 26090. The statute requires that this document be prepared and carried by delivery employees. This information would allow the Bureau to assess whether the applicant's planned operations are likely to comply with these requirements.

Proposed item 14 on Form BCC-LIC-020 requires the applicant to describe the process each delivery employee goes through upon arriving at a delivery destination and providing the customer with the cannabis goods. The Bureau's regulations require that delivery employees verify the identity and age of the customer before providing them with cannabis goods. Additionally, Business and Professions Code section 26090 requires that a copy of the delivery request receipt be maintained by the customer. Therefore, the delivery employee is required to provide a copy of this document to the customer upon completing the delivery. This information would allow the Bureau to assess whether the applicant's delivery protocols are consistent with these requirements.

Proposed item 15 on Form BCC-LIC-020 requires the applicant to describe the process that a delivery employee goes through upon returning to the licensed premises after concluding deliveries. This information allows the Bureau to assess whether this process is likely to comply with the regulatory requirements as well as whether the proper documentation is occurring to reduce the risk of theft or other loss at this stage.

Proposed section 16 on Form BCC-LIC-020 requires the applicant to describe the applicant's methods of auditing the activities of delivery employees to ensure that cannabis goods are not lost or stolen. There is an increased risk of loss or theft when a delivery employee carries cannabis goods with them while conducting deliveries. This information would allow the Bureau to assess whether the applicant is taking all the necessary steps to reduce this risk. Additionally, this information will allow the Bureau to determine whether the applicant's methods for auditing delivery employees is likely to be effective in reducing theft and identifying any loss of cannabis goods.

Proposed subsection (c)(30) would require that microbusiness applicants include a detailed description of the applicant's operating procedures required by this proposed section for each cannabis activity the applicant intends to engage in. This is necessary because microbusiness applicants can engage in cultivation and manufacturing which are not activities that are regulated by the Bureau, therefore only these applicants would need to provide cultivation and/or extraction and infusion methods.

Proposed subsection (c)(31) would require that applicant's for a testing laboratory also provide the operating procedures required under proposed chapter 6 of this division. This requirement is repeated in the application for clarity so that applicants may have all the required materials for an application listed in one section.

Proposed subsection (c)(32) would require that applicant's provide a limited waiver of sovereign immunity if applicable as required under proposed section 5009. This

requirement is repeated in the application for clarity so that applicants may have all the required materials for an application listed in one section.

Proposed subsection (c)(33) would require that applicants provide evidence of exemption from, or compliance with, the California Environmental Quality Act as required by proposed section 5010. This requirement is repeated in the application for clarity so that applicants may have all the required materials for an application listed in one section.

§ 5003. Designation of Owner

Proposed subsection (a) provides that an application must be submitted by an owner, defined under Business and Professions Code section 26001(al). This subsection is necessary so that the Bureau has at least one person identified as an owner to act on behalf of the business and who will submit required documentation.

Proposed subsection (b) further specifies who is considered an owner under the statutory definition for clarity. The subsection also establishes that an individual participating in the direction, control, or management of the person applying for a license can include a general partner of a commercial cannabis business organized as a partnership, a non-member manager or managing member of a commercial cannabis business organized as a limited liability company, an officer or director of a commercial cannabis business organized as a corporation, or any individual that assumes responsibility for the licensee. Subsection (c) provides that an entity with a 20 percent or more aggregate ownership interest in the person applying for licensure must include the chief executive officer and/or members of the board of directors of the entity as owners of the commercial cannabis business.

This section is necessary to clarify what types of individuals participate in the direction, control, or management of a business or corporate entity, so as to be included on an application for licensure. This information is essential in identifying the true and correct individuals that are owners of a commercial cannabis business. The true and correct identities must be provided because MAUCRSA requires licensing authorities to make a complete and thorough determination of a person's suitability for licensure, including consideration of an owner's history of convicted offenses that are substantially related to the qualifications, functions, or duties of the profession for which application is made, pursuant to Business and Professions Code section 26057. This is to ensure that the Bureau is carrying out the statutory mandate for public protection as the highest priority, by licensing only qualified persons.

§ 5004. Financial Interest in a Commercial Cannabis Business

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 agreement to receive a portion of the profits of a commercial cannabis business, 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. This is necessary to provide guidance to

applicants that a financial interest is not just owning shares of the company but also receiving a financial benefit from the company.

Proposed subsection (b) provides what the license application shall include for a person with a financial interest in the applicant. This is necessary so that the Bureau can identify each person with information unique to that person.

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.

§ 5005. Personnel Prohibited from Holding Licenses

This section prohibits certain individuals from holding a license issued by the Bureau, or having any direct or indirect ownership interest in any commercial cannabis business operating under a cannabis license. Such prohibited individuals are those whose professional duties include the enforcement of MAUCRSA or any other legal provisions regarding the sale, use, possession, transportation, distribution, testing, manufacturing, or cultivation of cannabis goods. Proposed subsections (a) and (b) clarify these individuals to include any such persons employed by any agency of the State of California, any of its political subdivision, and any persons employed in any district attorney's office, sheriff's office, city attorney's office, or as a peace officer in the State Department of Justice.

Proposed subsection (c) specifies that the individuals identified in subsection (a) and (b) may have any ownership interest, directly or indirectly, in any business to be operated or conducted under a cannabis license. Proposed subsection (d) clarifies that this section does not apply to those holding a license in his or her capacity as an executor, administrator or guardian.

Without restrictions on certain types of commercial cannabis business owners, individuals tasked with carrying out and enforcing the provisions of MAUCRSA could legally own or hold an interest in commercial cannabis businesses. This would create either the appearance of a conflict or an actual conflict of interest. This section is necessary to ensure that certain personnel execute their duties and obligations in a fair and objective manner on behalf of the State of California, without the risk or threat of partiality or bias.

§ 5006. Premises Diagram

Proposed section 5006 is necessary to clarify that the premises must meet the requirements of the Act and the regulations and to clarify what specific information is required to be

included on a premises diagram. Business and Professions Code section 26051.5, subdivision (c) requires that an applicant for licensure provide a complete detailed diagram of the proposed premises wherein the license privileges will be exercised, with sufficient particularity to enable ready determination of the bounds of the premises. The statute also requires that such a premises diagram includes all boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, common or shared entryways, and a brief description of the principal activity.

Proposed subsections (a) and (b) include the statutory requirements, for purposes of clarification, and explain to the applicant that the diagram will be used by the Bureau to determine whether the premises meets the requirements of the Act and the regulations. Proposed subsections (c) and (d) require the premises diagram to identify specific areas of commercial cannabis activity, designation of limited-access areas, as well as the location of all security cameras, with an assigned number to each camera for identification purposes. Subsection (c) also clarifies the specific types of commercial cannabis activity that must be identified, including, but not limited to, storage, batch sampling, loading or unloading of shipments, packaging and labeling, customer sales, loading for deliveries, extraction, growing, or processing.

Proposed subsections (e) and (f) require the premises diagram to be to scale, and drawn in black-and-white print only, without any highlighting. Proposed subsections (g) and (j) clarifies that a complete diagram also includes the entirety of a property and its uses, including residences with separate and distinct markings, even when the proposed premises consists of only a portion of that property. Proposed subsection (h) further provides that a property with two or more proposed premises must clearly show the designated entrances and walls under the exclusive control of the applicant for the premises as well as those for each additional premises, as Business and Professions Code section 26001(ap) requires each premises to be a contiguous area and occupied by only one licensee. Further, proposed subsection (h) clarifies that certain areas on the property where cannabis activity does not occur may be common or shared areas. Proposed subsection (i) clarifies that a microbusiness application that includes cultivation activities will have additional requirements, as required by statute, and further clarified in Section 5501 of the regulations. Lastly, proposed subsection (j) would clarify that if a premises is located on only a portion of a property that also contains a residence, then the diagram must clearly show the designated buildings for the premises and the residence.

This section is necessary to establish what is considered a complete and detailed premises diagram. A scaled, thorough, and legible diagram will allow the Bureau to appropriately, and within a reasonable timeframe, evaluate the application for compliance with the law. The information required in this section is needed to assist in clearly identifying with sufficient particularity, the boundaries and characteristics of the premises and land. Not only is this required by statute, but it will also allow the Bureau to ensure that the premises meets all legal requirements and that the licensee is the only one in control of the premises. Highlighting and colored print on the premises diagram are not allowed as any highlighting or colored print often will not translate to secondary printed copies, so any nuances detailed in color or highlighting will be rendered useless. Black-and-white print will ensure that the

diagram is usable if copied. Additionally, clarifying that this section applies to microbusinesses in addition to the requirements in the microbusiness section, assists the applicant with compliance.

§ 5007. Landowner Approval

Business and Professions Code section 26051.5(a)(2) requires that an applicant submit with the application “evidence of the legal right to occupy and use the proposed location.” This section describes the specific documentation required of an applicant to demonstrate the owner of the real property upon which the proposed premises will be located has approved the use of the property for commercial cannabis activity.

Proposed subsection (a) requires that when an applicant is not the owner of the real property upon which the proposed premises will be located, the applicant must obtain a document from the owner of the real property that states the applicant has the right to occupy the property and permission to conduct commercial cannabis activity on the property. It also requires a copy of the rental agreement, if one exists. This section is necessary to specify what documentation an applicant must obtain from the owner of the real property in order to provide the Bureau with “evidence of the legal right to occupy and use the proposed location.”

Proposed subsection (b) requires that if the applicant owns the real property upon which the proposed premises is located, the applicant shall submit a copy of the title or deed to the property. This section is necessary to specify what documentation the Bureau will accept as “evidence of the legal right to occupy and use the proposed location.”

Proposed subsection (c) specifies that if the landowner is a trust then the landowner approval shall come from the person that holds equitable title in the real property. This section is necessary to clarify who must provide the landowner approval when the property is held in trust to ensure the person who legally controls the property provides permission for the activity.

This section benefits applicants by providing clear direction on what is required to meet the statutory requirement. It also assists the Bureau because applicants will be able to provide the evidence the Bureau needs when they submit their application. Accurate information in the application ensures that the Bureau can process the application efficiently.

§ 5007.1 Electronic Signature

Proposed section 5007.1 would clarify that electronic signatures will be accepted on all documents received by the Bureau and required under the Act or the regulations. This is necessary to clarify that the Bureau will accept electronic signatures, in compliance with relevant provisions of the Uniform Electronic Transactions Act commencing at Civil Code section 1633.1, and as defined under Civil Code section 1633.2, subdivision (h).

The proposed section is necessary to provide direction and guidance to a licensee or applicant who may want to submit an electronic signature for any form or document required under the Act or regulations. This proposed section is also beneficial because the Bureau receives questions regarding the use of electronic signatures. Clarifying that

electronic signatures are acceptable for any required document will help answer these concerns on a more global level and minimize the time spent by licensees and applicants in having to contact the Bureau, which could postpone the submission of any required documents. The Bureau excepts documents required to be notarized from an electronic signature as, at this time, the notary requirements do not allow for electronic signature.

§ 5008. Bond

Business and Professions Code section 26051.5(a)(10) requires that all applicants provide proof of a bond to cover the costs of destruction of medicinal cannabis or medicinal cannabis products if necessitated by a violation of licensing requirements. Additionally, Business and Professions Code section 26070(a)(2) specifically requires that distributor licensees be bonded at a minimum level established by the licensing authority. Lastly, the Bureau developed a bond form which was approved by the California Department of Justice and can be located under Title 11, California Code of Regulations, Article 56, at section 118.1.

This section is necessary to fulfill the statutory requirement that the Bureau establish a minimum level of bond. This section establishes the bond amount minimum of \$5,000. The Bureau looked at other states that had required a bond and found that it was difficult if not impossible for licensees in other states to obtain a bond. The Bureau determined that \$5,000 was a high enough amount to cover destruction while still being low enough to be reasonably obtained by licensees.

§ 5009. Limited Waiver of Sovereign Immunity

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 section 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.

Proposed subsection (a)(1) requires 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 (a)(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(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 non-compliance. 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.

§ 5010. Compliance with the California Environmental Quality Act (CEQA)

The proposed section is necessary to inform applicants of the information necessary to fulfill the application requirement regarding the California Environmental Quality Act (CEQA).

CEQA is a state law that requires state and local government agencies to identify the significant environmental impacts of their actions and to avoid or reduce those impacts to the extent feasible. A public agency must comply with CEQA when it undertakes an activity defined by CEQA as a “project.” A project is an activity undertaken by a public agency or a private activity which must receive some discretionary approval from a

government agency (meaning that the agency can use its judgment in deciding whether and how to carry out or approve a project), which may cause either a direct physical change in the environment or a reasonably foreseeable change in the environment. The laws and rules governing the CEQA process are contained in the CEQA statute (Pub. Resources Code, § 21000 et seq.), its implementing guidelines (Cal. Code Regs., tit. 14, § 15000 et seq. [CEQA Guidelines]), published court decisions interpreting CEQA and its implementing guidelines, and locally adopted CEQA procedures.

The Bureau is subject to the requirements of CEQA because the Bureau licenses commercial cannabis activities that have the potential to impact the environment and the Bureau may impose conditions on its licensees. Prior to issuing a license, the Bureau must ensure that the appropriate level of environmental review under CEQA is complete.

Proposed subsection (a)(1) defines “project” as the commercial cannabis activity or activities for which an annual license application is submitted to the Bureau and which requires the Bureau to engage in discretionary review. This is necessary because “project” is used throughout the regulations. The proposed section is consistent with the term “project” as defined under CEQA Guidelines, § 15378 (a)(3).

Proposed subsection (a)(2) defines “CEQA Guidelines” as the Guidelines for Implementation of the California Environmental Quality Act codified at CEQA Guidelines, § 15000 et seq. This is necessary because the term “CEQA Guidelines” is used throughout the Bureau’s CEQA regulations.

Proposed subsection (a)(3) defines “environmental document” as having the same meaning as section 15361 of the CEQA Guidelines. Environmental documents are prepared by the applicant or the local jurisdiction that analyze the commercial cannabis activity or activities and which assesses whether the project has the potential to generate significant adverse environmental impacts. This is necessary to specify the type and scope of documentation that may be provided as evidence of compliance with CEQA.

Proposed subsection (b) allows the applicant to provide evidence of compliance with CEQA by submitting a copy of an environmental document previously certified or adopted by the local jurisdiction that evaluated the project. This requirement is necessary to eliminate redundancy in the environmental review process of a project for which a lead agency has completed an environmental review and determined the project’s potential impacts. This is also necessary to ensure that the Bureau completes the appropriate level of environmental review under CEQA, prior to issuing a license.

Proposed subsection (c) requires that the applicant submit enumerated information, if a previously certified or adopted environmental document is not available or does not exist, and if the Bureau does not determine that the project is exempt from CEQA. This is necessary to notify applicants of the documentation necessary to enable the Bureau to determine what type of environmental document should be prepared. This also ensures that the Bureau has enough information to complete the appropriate level of environmental review under CEQA.

Proposed subsection (c)(1) requires the applicant to provide information about the project location and surrounding land uses. This is necessary for the Bureau to accurately identify the physical location of the premises, existing conditions at the premises, and any land use restrictions. Requiring the applicant to provide information about the project location and surrounding land uses is necessary for the Bureau to assess whether a project has the potential to adversely impact the environment and to determine the type and scope of environmental documentation required for the project.

Proposed subsection (c)(1)(A) requires the applicant to provide a description of the project location including street address, city, county, Assessor's Parcel Number, major cross streets, general plan designation, zoning designation, and any other physical description that clearly indicates the project site location. This is necessary for the Bureau to verify the physical project premises and identify the area in which significant environmental effects could occur because of the project, either directly or indirectly.

Proposed subsection (c)(1)(B) requires the applicant to provide a description of the surrounding land uses and zoning designations within one-half mile radius of the project and to list the abutting land uses. This is necessary for the Bureau to identify any inconsistencies or incompatibilities between the proposed project and the local land use plan, policy, or regulation of an agency with jurisdiction over the project, including, but not limited to the general plan, specific plan, local coastal program or zoning ordinance.

Proposed subsection (c)(1)(C) requires the applicant to provide a vicinity map and aerial image to show the project location. This is necessary for the Bureau to visually assess the existing physical conditions at the project premises and the surrounding areas where significant environmental effects could occur because of the project, either directly or indirectly.

Proposed subsection (c)(1)(D) requires the applicant to provide photographs, not larger than 8 ½ by 11 inches, of the existing visual conditions as observed from the publicly accessible vantage point(s) around the project. This is necessary for the Bureau to visually assess whether the project may have a significant impact on a scenic vista, scenic resource, or the existing visual character or quality of a site and its surroundings. This also enables the Bureau to visually assess the existing physical conditions at the project premises and the surrounding areas where significant environmental effects could occur because of the project, either directly or indirectly. The proposed photograph size and vantage point parameters are necessary for administrative efficiency and to inform the applicant of photograph size constraints.

Proposed subsection (c)(2) requires the applicant to provide a project description. This is necessary for the Bureau to evaluate the totality of potential impacts and the physical conditions that exist within the area which will be affected by a proposed project. The specific impacts for which information is required include, but are not limited to, aesthetics; air quality; energy use; greenhouse gas emissions; hazards, hazardous materials, and human health impacts; and transportation and traffic.

Proposed subsection (c)(2)(A) requires the applicant to provide a description of the activities included in the project application and identify any other commercial cannabis

activity or activities occurring at the premises. A separate license is required for each of the applicant's commercial cannabis activities occurring at the premises and licensed by the Bureau, except in the case of microbusiness licenses. Because of this, the applicant may hold multiple commercial cannabis licenses issued by the Bureau, each of which are associated with specific, potential environmental impacts that must be considered simultaneously. Therefore, the proposed subsection is necessary for the Bureau's evaluation of all activities occurring at the premises which, when considered together with proposed project activities, may be considerable, compound, or increase other environmental impacts.

Proposed subsection (c)(2)(B) requires the applicant to quantify the project size (total floor area of the project) in square feet and the lot size on which the project is located, in square feet. This is necessary for the Bureau to consider the precise boundaries of the project's physical impact area.

Proposed subsections (c)(2)(C) and (c)(2)(D) specify the information that the applicant must submit about any other related public agency permits and approvals and other activities at the premises that may have significant impact on the environment. Specifically, this section requires the applicant to disclose to the Bureau whether the applicant is licensed by, or has applied for licensure from, the California Department of Food and Agriculture or the California Department of Public Health to engage in commercial cannabis activity at the proposed premises. This is necessary to inform the Bureau of any related environmental review and consultations requirements and to identify the other activities occurring at the premises which, when considered together with proposed project activities, may be considerable, compound, or increase other environmental impacts. This is also necessary to ensure that the Bureau addresses the environmental impacts of the project and can coordinate, when appropriate, with local jurisdictions and other public agencies.

Proposed subsection (c)(2)(E) requires the applicant to provide information about the potential transportation and traffic impacts of the proposed project. Specifically, the applicant must estimate the number of anticipated employees onsite, occupancy during operating hours, and frequency of deliveries or shipments originating from and/or arriving to the project site and describe the anticipated transportation activity at the project site including the effects of the project related to public transit, bicycle, or pedestrian facilities. This is necessary for the Bureau's assessment of whether the transportation and traffic activities associated with the project require mitigation measures or additional analysis to reduce or avoid potential, significant impacts.

Proposed subsection (c)(2)(F) requires the applicant to identify the location, type, and quantity of hazardous materials, as defined by the Health and Safety Code section 25260, that are stored, used, or disposed of at the project site and a copy of the Hazardous Material Business Plan (HMBP) prepared for the premises, if any. This is necessary for the Bureau to evaluate the potential for releases of hazardous materials from routine transport, use, and disposal; whether there is a significant hazard because of potential releases of hazardous materials from accident conditions; and whether the proposed project would create

substantial hazards for bureau staff, the public, and firefighters and first responders from commercial cannabis activity.

Proposed subsection (c)(2)(G) requires the applicant to discuss whether the project will increase the quantity and type of solid waste, as defined by the Public Resources Code, section 40191, or hazardous waste, as defined by the Health and Safety Code, section 25117, that is generated or stored onsite. This is necessary because it enables the Bureau to evaluate the potential landfill capacity issues that may be generated by the project.

Proposed subsection (c)(2)(H) requires the applicant to describe the project's anticipated operational energy needs; identify the source of energy supplied for the project and the anticipated amount of energy per day; and explain whether the project will require an increase in energy demand and the need for additional energy resources. This is necessary for the Bureau to assess the potential for cannabis business operations to generate greenhouse gas (GHG) emissions, either directly or indirectly, that may have a significant impact on the environment. This is also necessary for the Bureau to identify any conflicts with an applicable plan, policy, or regulation adopted to reduce the emissions of GHGs, and whether the operations will result in wasteful, inefficient, and unnecessary consumption of energy, or cause a substantial increase in energy demand and the need for additional energy resources.

Proposed subsection (c)(3) specifies that the Bureau will consider, for purposes of evaluating compliance with CEQA, both the individual and cumulative impacts of all commercial cannabis activities occurring at the premises. This section is necessary to inform the applicant of the scope of the Bureau's review. The broad scope of the Bureau's review is necessary to ensure that the Bureau addresses the environmental impacts of the project and which may require mitigation measures or alternatives to avoid or lessen the potential impacts, consistent with the directives of CEQA.

§ 5010.1. Review of Previously Prepared Environmental Documents Pursuant to CEQA

Proposed subsection (a) specifies that when the project has been evaluated in a previously certified or adopted environmental document, the Bureau will evaluate the project as a responsible agency as provided in section 15096 of the CEQA Guidelines. This subsection is consistent with the requirements of the CEQA Guidelines and is added for the clarity of prospective applicants. Consistent with section 15096 of the CEQA Guidelines, this subsection is necessary to eliminate redundancy in the environmental review process of a project for which a lead agency has already completed environmental review and determined the project's potential impacts.

Proposed subsection (b) specifies that the Bureau may require subsequent environmental review if one or more of the events outlined in Public Resources Code section 21166 or section 15162 of the CEQA Guidelines occurs. These events may include, for example, the occurrence of substantial changes in the project or the surrounding circumstances, or substantial new information demonstrating that the project may have new or more adverse significant environmental impacts, after the preparation of an environmental document. This subsection cross-references the relevant CEQA statute and CEQA Guidelines sections

for clarity and enables the Bureau to require the applicant to provide additional information or conduct additional environmental review. This section also enables the Bureau to impose additional conditions on the applicant to avoid or lessen such impacts. This subsection is necessary to ensure that the Bureau, addresses all environmental impacts, including those which may arise after the preparation of an environmental document.

§5010.2. CEQA Exempt Projects

Proposed subsection (a) allows the applicant to submit documentation to the Bureau demonstrating that the project is exempt from further environmental review pursuant to CEQA because the project falls within a class of projects under CEQA Guidelines, sections 15300 – 15333 that have been determined not to have significant effects on the environment. This is necessary to inform applicants that the Bureau will consider whether projects are categorically exempt from CEQA, such that no further environmental review is required.

Proposed subsection (b) specifies the required information in support of a determination that the project is exempt from further environmental review under CEQA: the project location and surrounding land use, project description, and a written justification to support a determination that the project is categorically exempt that lists the category and class and explains of how the project fits the exemption. This is necessary to provide clarity regarding the information of the Bureau will need from the applicant to confirm whether a project falls under a categorical exemption under CEQA.

Proposed subsection (b)(1) requires the applicant to provide information about the project location and surrounding land uses as required in section 5010 of this division. This is necessary for the Bureau to accurately identify the physical location of the premises, existing conditions at the premises, and any land use restrictions. Requiring the applicant to provide information about the project location and surrounding land uses is necessary for the Bureau to assess whether a project has the potential to adversely impact the environment and to determine type and scope of environmental documentation required for the project.

Proposed subsection (b)(2) requires the applicant to provide a project description as required in section 5010 of this division. This is necessary for the Bureau to evaluate the totality of potential impacts and the physical conditions that exist within the area which will be affected by a proposed project. The specific impacts for which information is required include, but is not limited to, aesthetics; air quality; energy use; greenhouse gas emissions; hazards, hazardous materials, and human health impacts; and transportation and traffic.

Proposed subsection (b)(3) requires the applicant to provide a written justification to support a determination that the project is categorically exempt that lists the category and class and explains of how the project fits the exemption. This subsection further specifies that the justification shall demonstrate that none of the exceptions to categorical exemptions described in section 15300.2 of the CEQA Guidelines apply to the project. This is necessary so that applicants know what information to submit to the Bureau; this information will inform the Bureau of the specific categorical exemption being requested

and enable the Bureau to determine whether the applicant's justification supports an exemption and that no exception to the exemption applies.

Proposed subsection (c) specifies that, upon reviewing the information submitted by the applicant, if the Bureau determines that the project is exempt from further CEQA review and approves an application for licensure, the Bureau will file a Notice of Exemption within five working days after approval of the project, consistent with Chapter 3 of the CEQA Guidelines.

§5010.3. Preparation of Environmental Documents by Applicant

Proposed section 5010.3 allows the Bureau to charge the applicant for the costs of preparation for any supplemental environmental document as well as the Bureau's costs for procedures to comply with CEQA if the Bureau determines that a project does not qualify for an exemption, or that the circumstances described in section 21166 of the Public section 15162 of the CEQA Guidelines require subsequent environmental review. This section is necessary to address situations where the Bureau determines that a project does not qualify for an exemption, or that the previously certified environmental document does not adequately address all the project impacts, necessitating subsequent environmental review. This section clarifies to applicants that they will be responsible for the preparation, including costs, of subsequent environmental documentation.

§ 5011. Additional Information

Business and Professions Code section 26051.5 (a)(7) states that the Bureau may require additional information in the application. Proposed section 5011 clarifies that the Bureau may require additional information and provides specific information on how the deadline for submittal of the additional information will be determined by the Bureau.

The Bureau has listed everything it will need to process applications in the application. In some cases additional information may be needed to verify or clarify something provided in the application. This proposed section is necessary to provide the Bureau with the authority and flexibility to request additional information when it needs to do so in order to fully assess the application.

§ 5012. Incomplete Applications

The regulation is necessary for the Bureau to implement licensing of commercial cannabis businesses under the MAUCRSA and specifically implement the application review process. The Bureau anticipates that it will receive incomplete applications. This proposed regulation specifies how the Bureau will provide notice to the applicant when it determines an application is incomplete, that the applicant has one year to correct the deficiencies and if the applicant fails to do so then the application is considered abandoned. The notice provided for shall be provided in accordance with Business and Professions Code section 124 applicable to licensing entities within the Department of Consumer Affairs and its provisions are referenced for clarity. The proposed regulation also clarifies that an applicant may reapply anytime following an abandoned application and that the Bureau will not refund application fees for incomplete applications. As the Bureau does not reach a

decision on an abandoned application, reapplying at any time allows an applicant to cure an issue and not have to wait to reapply. Application fees are not refundable because the Bureau must review the application to determine that it is incomplete.

§ 5013. Withdrawal of Application

The Bureau anticipates that some applicants may decide that they do not want to go through with licensure for a number of reasons. This may include changes in ownership or changes in premises after submission of an application. This section allows a withdrawal any time before the Bureau makes a decision on the application. However, the application fee will not be refunded because the Bureau will spend time on processing an application submitted even if it is later withdrawn. The regulation also contains a provision consistent with Business and Professions Code section 118, applicable to licensing entities within the Department of Consumer Affairs so that applicants are aware of this provision. This proposed section is necessary to provide applicants with the process for withdrawing their applications and the effects and consequences of withdrawing.

§ 5014. Fees

Proposed section 5014 implements the Bureau's authority to collect fees in connection with its regulatory activities under Business and Professions Code section 26012(b). Proposed subsection (a) addresses the application fees of \$1,000 per application and \$500 when modifying a premises, were based on what the Bureau believes is necessary to evaluate the application and reasonable enough not to deter applications. 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 fees outlined in subsections (c) and (d) 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. Subsection (e) indicates 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 to ensure the Bureau will be able to cover its costs as required by statute. Subsection (e) provides clarity for prospective licensees regarding whether the license fee is non-refundable. This is necessary because the Bureau will incur costs of licensing and enforcement during the license period, even if a licensee quits cannabis activity during the licensure period.

§ 5015. Payment of Fees

The proposed regulation is necessary to support the Bureau's regulatory program. The Bureau is authorized to collect fees in connection with its regulatory activities under section 26012, subdivision (b) of the Business and Professions Code. Subsection (a) is necessary because it clarifies what methods applicants for licensure may use to remit payments to the Bureau based on the Bureau's operational abilities.

Subsection (b) is necessary because it provides additional clarification for payments remitted by debit or credit card, by specifying that payment through these methods shall be done via the Bureau's online licensing system. The subsection also clarifies that if an applicant chooses to pay via debit or credit card, there may be additional fees imposed by the third-party vendor that will be processing payments. The Bureau currently can only accept credit or debit card payments through this method.

The penalty outlined in subdivision (c) is necessary to address circumstances where an applicant for licensure or licensee pays an amount less than the appropriate licensing fee. Failure to pay fees on time or pay in part creates additional workload for the Bureau, thus additional fees are required. It clarifies potential penalties and provides that failure to pay appropriate fees may also result in disciplinary action. This section also allows the Bureau to waive any penalties in its discretion to account for circumstances which impeded the ability to pay on time.

§ 5016. Priority Licensing

Business and Professions Code section 26054.2 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. Proposed section 5016 is necessary to address the information needed by the Bureau to evaluate whether an applicant meets the criteria for priority licensing, and clarifies the criteria specified in Business and Professions Code section 26054.2. Proposed subsection (a) clarifies that priority licensing is only available for annual licenses, and not applicable to temporary licenses or cannabis event organizer licenses, licenses not contemplated by priority licensing as they did not already exist before the Act was in place. This clarification is necessary to let applicants know for what license types they may receive priority licensing. Proposed subsection (b) provides how an applicant may establish eligibility for priority licensing, either: (1) a licensee may be identified on a list from the local jurisdiction; or (2) a licensee may provide 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. Thus, providing alternate methods to satisfy this threshold is necessary. The proposed section also provides that priority licensing will not be provided by the Bureau after December 31, 2019. Including the time period for the ending of priority licensing is included for clarity and consistency as the statute becomes inoperable after December 31, 2019.

§ 5017. Substantially Related Offenses and Criteria for Rehabilitation

Business and Professions Code section 26057, subsection (b)(4) states that the Bureau may deny an application if the applicant has been convicted of an offense that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made. This section is necessary because it provides clarity regarding the Bureau's considerations in its evaluation of an applicant's offenses that are substantially related to the qualifications, functions, or duties of operating a commercial cannabis business, consistent with Section 26057. Business and Professions Code section 26057 requires the Bureau to conduct a thorough review of the nature of an applicant's convictions, including evidence of rehabilitation from criminal acts that are substantially related to the qualifications, functions, or duties of conducting commercial cannabis activity.

Proposed subsection (a) specifies convictions that would be considered substantially related to the qualifications, functions, or duties of the business requesting licensure from the Bureau. This subsection is important because it informs applicants of the specific convictions that may affect an application for licensure. Proposed subsections (a)(1)—(a)(5) identify convictions that are considered substantially related offenses in Business and Professions Code section 26057(b)(4). The Bureau is required to create regulations that will protect the health and welfare of the public; accordingly, the Bureau has determined that a history of committing the crimes identified in subsections (a)(1)—(a)(5) are relevant to licensure because they may affect the applicant's ability to perform the requested commercial cannabis activity. Moreover, the proposed regulation subsections repeat the offenses identified in the Business and Professions Code for the convenience of applicants. By restating potential reasons for denial, along with other offenses that are considered substantially related, the proposed regulations will not require a reader to refer to both the regulations and the Business and Professions Code to determine which offenses may be considered substantially related to licensure from the Bureau.

Proposed subsection (b) clarifies that a felony conviction for offenses involving controlled substances may not be considered substantially related to the duties of the business the applicant is submitting an application for if certain criteria are met. This subsection is necessary to inform potential applicants regarding how the Bureau will treat prior convictions for which a sentence was effectively served and repeats the requirement of Business and Professions Code section 26057(b)(5) for clarity. The proposed subsection also specifies that a conviction for a controlled substance felony subsequent to licensure will be grounds for revocation. This subsection is necessary to provide applicants and

licensees with fair warning that certain post-licensure actions may impact their ability to retain a license.

Proposed subdivision (c) clarifies the factors that the Bureau will consider in determining whether an applicant has effectively been rehabilitated following a conviction. The criteria the Bureau will consider for rehabilitation will aid the Bureau's determination of whether an applicant is fit for licensure. Determining whether an applicant is fit for licensure requires the consideration of a variety of factors. This section is necessary to inform potential applicants of the factors that will be considered in this portion of the application process.

Proposed subsection (c)(1) requires the Bureau to consider the nature and severity of the act or offense. This is required because the nature and severity of the offense may provide some indication of whether the offense will be repeated. The Bureau is required to create regulations that will protect the health and welfare of the public. Accordingly, the Bureau has determined that it should not provide licenses to individuals who have a high risk of repeating their past severe criminal acts.

Proposed subsection (c)(2) requires the Bureau to consider whether the offense would still be considered a crime in light of the current legislative framework. The Bureau recognizes that the sale of cannabis has historically been illegal; in fact, it remains illegal in federal law. However, because the Bureau has been charged with licensing commercial cannabis businesses, it is important to consider whether the acts that the applicant was convicted of in the past are the very same acts the Bureau is issuing licenses to perform. This factor affects an applicant's fitness for licensure.

Proposed subsection (c)(3) requires the Bureau to consider the applicant's criminal record as a whole. This is required because the applicant's complete criminal record may provide some insight as to whether prior offenses will be repeated. The Bureau is required to create regulations that will protect the health and welfare of the public. Accordingly, the Bureau has determined that it should not provide licenses to individuals who are considered to have a high risk of repeating their past criminal acts.

Proposed subsection (c)(4) requires the Bureau to consider evidence of any act committed subsequent to the act or offense under consideration. This is required because an applicant's subsequent acts may provide some indication of whether the offense will be repeated. The Bureau is required to create regulations that will protect the health and welfare of the public. Accordingly, the Bureau has determined that in some instances it may not be reasonable to provide licenses to individuals who have an extensive history of criminal acts as there may be a high risk of repeating their past criminal acts.

Proposed subsection (c)(5) requires the Bureau to consider the time that has elapsed since commission of the act. This is required because the time that has passed since the commission of the act may provide some indication of whether the offense will be repeated. A lapse of a large amount of time since the offense was committed may be evidence that the applicant is unlikely to recommit the offense. The Bureau is required to create regulations that will protect the health and welfare of the public. Accordingly, the Bureau has determined that it should not provide licenses to individuals who have recently

committed an act, as there may be a high risk of the applicant repeating their past criminal acts.

Proposed subsection (c)(6) requires the Bureau to consider the extent to which the applicant has complied with any terms of parole, probation, restitution, or any other sanctions lawfully imposed against the applicant. This is required because this factor may provide some indication of whether the offense will be repeated. Compliance with the terms of parole, probation, restitution, or any other sanctions may demonstrate that an applicant will be less likely to repeat its past criminal acts.

Proposed subsection (c)(7) requires the Bureau to consider evidence of dismissal of the offense. Evidence of a dismissal indicates that a court for one reason or another has determined that the offense be dismissed from an applicant's record. This is an important factor in determining whether an applicant is fit for licensure because a court has determined the offense should not be included in the persons' criminal history.

Proposed subsection (c)(8) requires the Bureau to consider certificates of rehabilitation obtained by the applicant. This is required because a certificate of rehabilitation is direct evidence that a court believes that the applicant is rehabilitated. This should be considered by the Bureau in determining whether an applicant is fit for licensure.

Proposed subsection (c)(9) requires the Bureau to consider other evidence of rehabilitation submitted by the applicant. This provides some flexibility on the types of evidence that can be provided by an applicant and considered by the Bureau in determining whether or not an applicant is fit for licensure. This is important to allow the Bureau to consider as much evidence as possible and anything the applicant thinks is relevant before determining an applicant's fitness for licensure.

Proposed subsection (d) specifies that an individual who is denied for licensure may request a hearing to determine whether the applicant should be licensed. This section is necessary to inform applicants of their rights, following the denial of a license. The right to have a hearing upon the denial of a license is stated in Business and Professions Code section 26058. The provision is repeated for the convenience of the reader.

§ 5018. Additional Grounds for Denial of a License

The purpose of this proposed section is to define additional grounds for which the Bureau may deny a license. Business and Professions Code section 26057 states non-inclusive grounds for denial of a license. This proposed regulation is added to provide additional clarification to the Act and is necessary to provide transparency to the industry regarding additional reasons the Bureau may choose to deny a license.

When applying for a license from the Bureau, applicants are required to submit certain documents to the Bureau, including operating procedures and a diagram of their proposed premises. Subsections (a) and (b) of this proposed regulation clarify that the Bureau may deny an applicant whose premises does not comport with standards set in regulation or whose premises is substantially different from the premises diagram submitted to the Bureau. Subsection (b) clarifies that an applicant's premises is substantially different from the diagram of the premises submitted by the applicant, in that the size, layout, location of a

common entryways, doorways, or passage ways, means of public entry or exit, or limited-access areas within the licensed premises are not the same. This allows the Bureau to take action if the applicant misrepresents the premises in the diagram, therefore, ensuring that a license is not issued if the premises does not comport with the Act.

The Act authorizes the Bureau to inspect commercial cannabis premises to verify that commercial cannabis operations are operating in accordance with the Act. Subsection (c) of this proposed regulation will ensure that the Bureau is able to deny a license to an applicant that denies the Bureau access to their premises for the purposes of inspection.

Proposed subsections (d) and (e) specify that committing a material misstatement or failing to correct deficiencies on a license application is grounds for denial of a license. The Bureau relies on accurate information in the application to determine whether an applicant is qualified for licensure. It is imperative that the information provided be accurate. The Bureau has determined that these proposed subsections are necessary to deter material misstatements or deficiencies on applications and to clarify that the Bureau may deny an application if such misstatements or deficiencies were to occur.

Proposed subsection (f) provides that the applicant may be denied for a license for the Bureau if it has been denied a license, permit, or other authorization to engage in commercial cannabis activity by a state or local licensing authority. This is necessary because there are two other state licensing authorities and hundreds of local licensing authorities. If one of the other licensing authorities denies an applicant, the Bureau must be able to take that denial, and the reasons for that denial, into consideration.

Proposed subsection (g) provides that the applicant may be denied a license for failure to comply with the California Environmental Quality Act (CEQA, Division 13 (commencing with Section 21000) of the Public Resources Code). This is necessary because every discretionary approval, such as an application for licensure submitted to the Bureau for review, requires at least some environmental review pursuant to CEQA. Consistent with CEQA's review requirements, a license may not be approved if feasible alternatives or mitigation measures are able to substantially lessen the significant environmental effects generated by its approval.

Proposed subsection (h) provides that the applicant may be denied a license for failure to remit taxes as required under the Revenue and Taxation Code. This is necessary because license fees are based on the maximum dollar value of a licensee's planned operation. If applicants are not remitting their taxes as required under the Revenue and Taxation Code, it will be difficult for the Bureau to determine whether an applicant is paying the appropriate scaled license fee. Moreover, failure to pay taxes may have bearing on whether an applicant is fit for licensure.

Proposed subsection (i) provides that the applicant may be denied a license on any additional grounds as authorized by law. This is necessary because it provides some flexibility on the types of evidence that can be considered by the Bureau in determining whether an applicant is fit for licensure. This is important to allow the Bureau to consider as much evidence as possible before determining an applicant's fitness for licensure as a

licensee is expected to obey all laws applicable to the business operations, including those of general application in the state, not just those in the Act.

§ 5019. Excessive Concentration

In reviewing applications for licensure, Business and Professions Code section 26051, subdivision (c) requires the Bureau to consider if an excessive concentration of licensees exists in the area where a prospective licensee will operate. Proposed subsection (a) of the regulation clarifies what conditions will be considered “excessive concentration.” This subsection provides the Bureau mechanisms to aid its determination of whether issuing a license will result in an “excessive concentration” of licensees in a specific census tract, including: (1) the ratio of licensees to population within the census tract or census division; or (2) the ratio of retail licenses or microbusiness licenses to the population within the census tract, census division, or jurisdiction. This subsection is necessary as it establishes clear metrics for the Bureau’s determination of an “excessive concentration” of licensees in a given area and contains the statutory provisions for clarity and convenience.

Proposed subsection (b) fleshes out the definition for “Population within the Census Tract or Census Division” as the population as determined by the most recent United States decennial or special census. This subsection also enables applicants to provide additional evidence to establish that there has been an increase of resident population within a census tract or division. This subsection is necessary as it provides a uniform tool to determine the concentration of licensees within a given census tract or census designation. In addition, recognizing that the decennial census data may not be an accurate reflection of the current population, the subsection is necessary because it provides prospective licensees the opportunity to provide additional data that demonstrates that the population of a given census tract or census designation has increased.

Proposed subsection (c) further defines “Population in the County” as being determined by the most recent annual population estimate for California counties published by the Demographic Research Unit, State Department of Finance. This subsection is necessary to provide clarity on the data that will be considered in the determination of a given County’s population. It also assures a uniform data set will be used statewide for the determination of county population.

Proposed subsection (d) clarifies how often Bureau will determine the ratios in subdivision (a); specifically, the Bureau will update the ratios used to evaluate excessive concentration once every six months. This subsection is necessary as it assures the ratios used by the Bureau to evaluate excessive concentrations are as up-to-date as possible while not being adjusted so often it is confusing and burdensome.

To begin issuing licenses on January 1, 2018, the Bureau is authorized by section 26050.1 of the Business and Professions Code to issue temporary licenses to applicants that can demonstrate compliance with local requirements. Proposed subdivision (e) clarifies that excessive concentration will not be a factor considered in determining whether to grant, deny, or extend a temporary license under Business and Professions Code section 26050.1. This is necessary because it provides clarity regarding when the Bureau will consider excessive concentrations as a factor in a licensing action.

Proposed subsection (f) provides that an applicant may provide reliable evidence, to the satisfaction of the Bureau, that the denial of a license would unduly limit the development of the legal market so as to perpetuate the illegal market for cannabis and cannabis products. This subsection is necessary because it provides a mechanism for applicants to demonstrate why issuance of their license is warranted, even if they are located in an area with an excessive concentration of licensees.

§ 5020. Renewal of License

Section 26050, subdivision (d) of the Business and Professions Code provides that the Bureau shall establish procedures for the issuance and renewal of licenses. This proposed regulation section provides necessary elaboration on the renewal process.

Specifically, proposed subsection (a) requires that the Bureau receive a renewal form from a licensee no earlier than 60 calendar days before the expiration of the license and no later than the day before the license expires. This subsection is required because it clarifies when renewal applications must be submitted to the Bureau. Renewal applications are required to be submitted no earlier than 60 calendar days prior to the expiration so that the Bureau does not receive applications for renewal too early. Submitting renewal applications earlier than 60 days may increase the possibility that something changed between the renewal submission and approval. The Act only allows a license to be valid for 12 months, thus, any renewal must be done before the expiration date.

Proposed subsection (b) specifies that a licensee who does not submit a renewal application prior to the date the license expires is no longer authorized to conduct commercial cannabis business. This subsection is required to clarify that there is no grace period for expired licenses. Licensees are expected to renew their licenses in a timely manner, or cease all operations of the commercial cannabis operation to be in compliance with the 12-month license requirement in the Act.

Proposed subsection (c) provides that a licensee may submit a license renewal form for 30 calendar days after the license expires. Licensees are expected to renew their licenses in a timely manner. This requirement intends to deter licensees from routinely submitting late applications, past the 12-month license requirement of the Act. Any late renewal form under this subsection will be subject to a late fee equal to 50 percent of the applicable license fee required in subsection (a). In addition to deterring licensees from routinely submitting late renewal forms, this fee was determined to be nominal when compared to a licensee's lost revenue after having to cease operations upon license expiration.

Proposed subsection (d) specifies the information the applicant must provide to the Bureau for processing. The Act does not specify what a licensee needs to submit in an application for renewal. This proposed section is necessary to provide licensees with directions on the information that is required in the renewal application. The information required by subsection (d)(1)—(3) includes identification information for the licensee and licensed premises necessary to locate the correct license. Subsection (d)(4) contains the information necessary to determine the license fee. Subsection (d)(5) requires a confirmation that critical information which would require review by the Bureau has not changed. Subsection (e) reiterates the requirement for an annual waiver of sovereign immunity to ensure all licensees are subject to the same rules.

§ 5021. Denial of License

The Bureau is authorized to issue licenses to qualified applicants. Section 26057 of the Business and Professions Code outlines certain conditions for which an application for licensure or renewal should be denied. This proposed regulation is necessary to provide additional clarification to the Act and is necessary to provide transparency regarding denial procedures, and an applicant's recourse upon receipt of their denial.

Specifically, proposed subsection (a) reiterates the Bureau's ability to deny an application for licensure for the reader's convenience. This proposed subsection provides additional clarification to the Act and is necessary to provide transparency to the industry regarding reasons the Bureau may choose to deny a license. Proposed subsections (b) and (c) provide a procedural overview regarding how the Bureau is to notify an applicant of their denial and what an applicant may do to request a hearing on that denial. These subsections are necessary as they not only inform the industry on how the Bureau will contact an applicant to inform it that an application has been denied, but they provide a procedural overview on how applicants may seek review of the Bureau's decision. These standards are consistent with the Administrative Procedures Act applicable to licensing hearings.

§ 5022. Cancellation of License

The Bureau is authorized to create, issue, deny, renew, discipline, suspend, or revoke licenses under the Act. The purpose of this section is to specify when a license must be cancelled and when it may be cancelled.

Proposed subsection (a) requires a licensee that abandons or quits the licensed premises or who closes the licensed premises for a period exceeding 30 consecutive calendar days to request in writing that the Bureau cancel the license within 10 business days after closing. This section is necessary to provide licensees with direction on what circumstances require them to cancel their license. Moreover, this section assures that the Bureau will not devote staff resources to enforcing the Act and its implementing regulations on non-active licensees. This also allows the Bureau to revoke a license when the process is not followed so the public will not believe a canceled license is active. The person must also destroy and not display a revoked or canceled license as this could mislead the public.

Proposed subsection (b) allows the Bureau to cancel a license at any time upon request by the licensee if there are no outstanding fines or fees due to the Bureau and no pending disciplinary action(s). This is necessary to clarify the circumstances under which a licensee may request to cancel their license and to prevent a licensee from canceling a license to avoid disciplinary action.

Proposed subsection (c) recognizes that licensees may need to conduct necessary repairs or renovations that physically change, alter, or modify the licensed premises. This subsection allows the licensee to retain licensure for more than 30 consecutive calendar days to conduct these activities. This subsection is necessary to provide licensees the opportunity to make necessary repairs or renovations and remain licensed.

Proposed subsections (d) allows a licensee to request that the Bureau reinstate a revoked license prior to the expiration of the revoked license. This subsection is necessary to clarify the circumstances in which a licensee may seek reinstatement of their license. These sections are also necessary because they clarify how a licensee may communicate with the Bureau regarding its licensure status. In certain circumstances, there may be reasons for failure to comply with subsection (a) that warrant allowing the license to be reinstated. However, if the license expires before reinstatement, no license exists to reinstate therefore a new license application is necessary.

§ 5023. Business Modifications

The Bureau recognizes that the information provided as part of an application for licensure is not static and changes may arise. The purpose of this section is to require existing licensees to timely notify and apprise the Bureau of any changes to the information listed in the application; this assures that the Bureau has up-to-date information on its licensees and that the Bureau has the opportunity to determine whether certain changes affect licensure status. It also clarifies circumstances in which changes to ownership require the submittal of a new application for licensure.

Proposed subsection (a) is necessary to assure that all licensees maintain up-to-date copies of their standard operating procedures. This allows for the Bureau to effectively administer its inspection duties under the Act and assures that current standard operating procedures for each licensee, are available for the Bureau's review.

Business and Professions Code section 26051.5, subsection (a)(5) requires that a licensee who employs 20 or more employees provide a statement that the licensee will enter into or has entered into a labor peace agreement. Proposed subsection (b) clarifies that licensees who employed less than 20 employees and were not subject to this provision at the time the license was obtained, must comply with the requirements of the statute if at some point after licensure, they employ 20 or more employees and become subject to this provision. This section also specifies that once the licensee enters into a labor peace agreement it shall provide the Bureau with a copy of the signature page. Requiring the signature page is necessary to confirm that the licensee has entered into the labor peace agreement required by the Act.

Proposed subsection (c) is necessary to clarify the circumstances where a ownership change requires a new application. Specifically, if any new person acquires an ownership interest, then a new application is required. This is necessary to verify that owners satisfy the requirements for licensure. Specifically, this subsection enables the Bureau to verify ownership and conduct background checks on owners. This subsection also clarifies that licensees that acquire new owners may continue operating under their current license while the Bureau reviews their application under the new ownership so long as at least one owner will be remaining under the new ownership structure to allow for continuity of business, while observing the statutory requirement to vet owners. This is necessary for licensees to understand the circumstances where the business can continue operating during an ownership change and when the business would need to be shut down.

Proposed subsection (d) is necessary to clarify that anytime there is a change in persons with financial interest in the commercial cannabis business that do not meet the requirements for a new license, the licensee must submit this information to the Bureau. This is necessary because of the need for the Bureau to verify financial interests in commercial cannabis entities.

There may be some situations where a licensee has one license designation and may want to engage in both A and M licensed activities. Subsection (e) is necessary because it clarifies the procedures that a licensee must follow in order to request additional commercial activities under their license. It also clarifies that a licensee may not engage in the additional license designation activities until they have received formal approval from the Bureau to do so. This is necessary because A and M activities may only be allowed if it does not conflict with local ordinances; therefore, the Bureau must evaluate if the licensee can engage in the other designated activities.

Proposed subsection (f) is necessary because it clarifies that microbusiness licensees may request a modification to their existing microbusiness license to add additional licensed activities and outlines the procedure to do so. This subsection also clarifies that a licensee may not engage in the additional licensed activities until they have received formal approval from the Bureau to do so. This is necessary to allow the Bureau to determine if these activities can be allowed before the licensee begins engaging in them.

Business and Professions Code section 26053, subsection (d) requires a separate license for each location where a licensee engages in commercial cannabis activity. Consistent with this statutory requirement, proposed subsection (g) is necessary because it clarifies that anytime a licensee wishes to change the location of their licensed premises, a new application must be submitted.

§ 5024. Death, Incapacity, or Insolvency of a Licensee

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

§ 5025. Premises

The Act, in section 26053, subdivision (d) of the Business and Professions Code, requires that each premises upon which commercial cannabis activity is conducted be licensed.

Proposed subsection (a) further elaborates on the premises and by doing so ensures that applicants know how many licenses they will need for the areas upon which they will conduct their commercial cannabis activity and the requirements for each location. The premises on which commercial cannabis activity is conducted is subject to numerous requirements and inspection by the Bureau. Therefore, one designated area, with its own distinct address or suite number, which is occupied by one licensee, allows the Bureau to effectively inspect the area and allows for one responsible licensee who must ensure compliance with license conditions.

Proposed subsection (b) is necessary to clarify the limited circumstances in which a licensee may have the same licensed premises for adult-use and medicinal commercial cannabis activity. Specifically, this subsection provides that where a licensee holds both an A-designation and an M-designation for the identical type of commercial cannabis activity, adult-use and medicinal commercial cannabis activity can be located at the same location.

Proposed subsection (c) is necessary to clarify that licensees authorized to engage in retail activities may only sell cannabis goods to customers within their licensed retail premises or at a delivery address that meets the requirements of this division. Security is very important in operating a cannabis business. Allowing a licensee to utilize a pass-out window or slide-out tray may result in the licensee losing control over who enters the premises, which may lead to an increased risk of theft, diversion, or other unauthorized activity. A similar concern arises with deliveries from the retail premises to customer's motor vehicle. The risk of losing control over the premises is minimized with this subsection.

Section 26054 (a) of the Business and Professions Code prohibits licensees from selling alcoholic beverages or tobacco products at a premises licensed under this division.

Accordingly, subsection (d) clarifies that alcohol may not be stored or consumed at a licensed premises, thereby limiting the potential for licensees to violate this enumerated provision in the Act.

Proposed subsection (e) specifies that licensed premises must be separated another premises engaging in manufacturing or cultivation. This is necessary to ensure that the activity over which the Bureau has regulatory authority is clearly and physically separated from the physical space(s) over which other state licensing agencies may have authority. This is also necessary to avoid exposing licensees to the specific types of chemicals and possible contaminants at manufacturing and cultivation premises.

Proposed subsection (f) specifies that cannabis shall not be dispersed in the air throughout the premises by an oil diffuser or any other vaporizing device. This is necessary to ensure that licensees are not dispersing cannabis in the air which can impact and impair all persons within the premises, potentially without their knowledge.

Proposed subsection (g) specifies that an applicant or licensee may have a drive-in or drive-through window only if, prior to June 1, 2018, the licensee or applicant received local authorization for the activity or applied for a permit from the local authorizing agency. This is necessary to clarify the qualifying circumstances under which an entity may operate a drive-in or drive-through window, which only allows this activity if it was approved or in the approval process before the Bureau's regulation. This allows licensees who already have invested in this practice to continue those operations.

§ 5026. Premises Location

The purpose of this section is to provide added clarity on appropriate locations for a prospective licensee's premises. Proposed subsections (a) and (b), consistent with section 26054 of the Business and Professions Code, indicate that a licensed premises shall not "be located 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, unless a licensing authority or a local jurisdiction specifies a different radius." Where a local jurisdiction has issued a license or permit to conduct commercial activity at a premises that is located within the 600-foot radius identified above, subsection (b) identifies the types of evidence the Bureau will consider.

Subsections (c), and (d) are necessary for public health and safety by ensuring that the licensee is the only one in control of the licensed premises. Allowing a licensed premises that may only be accessed via another business or residence may result in the licensee losing control over who enters the premises, which may lead to an increased risk of theft, diversion, or other unauthorized activity. Additionally, an unlicensed person is not subject to the rules and regulations for operating a cannabis business. The risk of the licensee losing control over the premises is minimized with the location restrictions identified in these subsections.

Subsection (e) is necessary to assure that the Bureau is able to conduct timely inspections when needed. This subsection is also necessary to assure that the Bureau can effectively enforce its regulations and conduct thorough investigations, even if the only way to access the premises is controlled by another person or entity.

§ 5027. Physical Modification of Premises

In order for the Bureau to effectively carry out its duties under the Act, it is necessary to have accurate and up-to-date information on licensed premises. The purpose of this section is to specify that a licensee shall not make a physical change, alteration, or modification of the licensed premises that materially or substantially alters the licensed premises or the use of the licensed premises without the prior written approval of the Bureau.

Proposed subsection (a) requires the licensee to receive written approval from the Bureau prior to making any material alterations. Without requiring a licensee to update the Bureau of material alterations, there is no assurance that the changes are permitted within the statutory and regulatory framework. Without the affirmative duty of a licensee to notify the Bureau, a change may go a significant amount of time in noncompliance before discovery. Altering premises without notification could also hinder Bureau investigations and audits, make site visits take longer, and potentially be unsafe. By requiring an affirmative duty to

notify the Bureau of material changes, the regulations ensure that the Bureau is consistently aware of the shape, condition, and legality of licensed premises.

Proposed subsection (b) lists examples of material changes and is necessary to inform licensees of what premises changes will require prior approval from the Bureau. The changes listed may impact whether the premises are appropriate for licensure. Proposed subsection (c) provides the requirements of a request for approval of a physical change, alteration, or modification and is necessary to specify what a licensee must provide to the Bureau with the initial request. Proposed subsection (d) provides that a licensee shall provide additional documentation as requested by the Bureau, and is necessary for situations where the Bureau needs additional information in order to approve or deny the licensee's request for premises modification.

§ 5028. Subletting of Premises

This proposed section states that a licensee shall not sublet any portion of its licensed premises. The purpose of this section is to protect public health and safety by ensuring that the licensee is the only one in control of the licensed premises. Security is very important in operating cannabis business. Allowing a licensee to sublet any portion of the licensed premises may result in the licensee losing control over who enters the premises, which may lead to an increased risk of theft, diversion, or other unauthorized activity. Additionally, an unlicensed person is not subject to the rules and regulations for operating a cannabis business. By not allowing licensees to sublet the premises, the risk of the licensee losing control over the premises to a subtenant is eliminated. This section ensures that the licensee will have sole control over the licensed premises. More importantly, this section ensures that only the licensee will be responsible for visitors to the premises.

§ 5029. (RESERVE FOR FUTURE USE)

§ 5030. Licensee's Responsibility for Acts of Employees and Agents

The purpose of this proposed section is to clarify when the actions of a person acting for or employed by a licensee shall be deemed the actions of the licensee. Business and Professions Code section 26012, subdivision (a)(1) gives the Bureau the authority to regulate licenses for the transportation, testing, distribution, and sale of commercial cannabis. For the purposes of regulating and enforcing the actions of licensees, it is necessary for the Bureau to define and clarify when the actions of a person acting for or employed by a licensee will be considered the actions of the licensee. This will avoid situations in which licensees attempt to avoid responsibility for violations of the Act or regulations by having an agent or employee act for them. It will also ensure that the public safety is protected through compliance with the regulatory scheme.

§ 5031. Age Restriction

The purpose of this section is to clarify that employees working within a licensed premises and/or handling cannabis or cannabis products shall be at least 21 years of age. Business and Professions Code section 26140, subdivision (a)(3) prohibits an A-designated license

from employing or retaining persons under 21 years of age. Oftentimes, an M-designated license is co-located with an A-designated license. The Bureau finds that extending A-designated licensee employee age restrictions to employees of M-designated licensees is integral for the protection of minors. The Bureau recognizes that there may be some non-management or non-cannabis activities, such as internet technology or multimedia services, which do not require an employee to handle cannabis or work within the licensed premises; this regulation would permit the retention of persons under 21 years of age, provided the employee or contractor does not work within the licensed premises or handle cannabis.

§ 5032. Designated M and A Commercial Cannabis Activity

The purpose of this section is to protect public health and safety and ensure an effective method of tracking both adult-use and medicinal commercial cannabis goods by specifying the requirements for transactions between licensees. This section also recognizes the importance of providing licensees the ability to procure and sell product based on the commercial cannabis market's demands. In furtherance of these goals, subsection (a) specifies that all commercial cannabis activity shall be conducted by licensees. Subsection (b) provides that Bureau licensees may conduct business with other licensees irrespective of the "M" or "A" designation on their licenses. Subsections (c) and (d) specify who licensed distributors, retailers, and microbusinesses may sell goods designated as "For Medicinal Use Only," based on the Act's provisions related to medicinal cannabis.

§ 5033. Storage of Inventory

The purpose of this section is to preserve the safety and security of the licensed premises and the cannabis goods stored on site by providing licensees with rules for the storage of inventory of cannabis goods. It is important for the Bureau's licensees to secure their inventory in order to decrease the risk of theft or other crimes and to maintain the quality of the cannabis goods.

Proposed subsections (a) and (b) require that the storage area of an entity licensed by the Bureau to be in limited access area or restricted access area; no outside storage is allowed. This requirement assures that opportunities for diversion are limited. This also assures that temperature and humidity can be controlled. Temperature, light, and humidity alter the chemical composition of cannabis, and by storing product indoors, these conditions can be controlled for. Indoor storage also ensures that environmental contaminants like smoke and dust may be limited. For the same reasons, proposed subsection (c) requires all break rooms, changing rooms for employees, and bathrooms be separate from cannabis goods storage areas.

Proposed subsection (d) requires each location where cannabis goods are to be stored by separately licensed. This requirement is consistent with Business and Professions Code section 26053, subdivision (d), which requires a separate license for each location where an applicant engages in commercial cannabis activity.

§ 5034. Significant Discrepancy in Inventory

The Act recognizes that it is important the Bureau be aware of any inventory discrepancies to assist with preventing diversion. The statute does not define the term significant discrepancy in inventory. In order to provide licensees with a clear idea of when their notice requirements are triggered under the statute, this section is required. In order to avoid over reporting due to loss that is experienced in the regular course of business, the Bureau has decided to set the amount of a significant discrepancy at \$5,000 or 2 percent of the average monthly sales of the licensee, whichever is less. This threshold was determined based on information available about the costs of cannabis goods and typical losses in the course of business.

Subsection (b) elaborates on how average monthly sales shall be calculated. The Bureau has required a six month period which seems to be a reasonable amount of data to determine an average, when available.

Subsection (c) further provides that for the purposes of this section, the licensee's acquisition price shall be used to determine the value of cannabis goods in a licensee's inventory. This clarification is necessary because it assures that all licensees utilize the same methodologies to determine the value of their inventory.

§ 5035. Notification of Criminal Acts, Civil Judgments, Violations of Labor Standards, and Revocation of a Local License, Permit, or Other Authorization After Licensure

This section describes the licensee's notification requirements for specific events. Business and Professions Code section 26031 provides for discipline of a licensee for conviction of a crime or failure to comply with provisions of the Act or regulations adopted pursuant to the Act. Business and Professions Code section 26031 subsection (b) states that the revocation of a licensee's local license, permit, or other authorization terminates the ability of the licensee to operate in that jurisdiction. Section 26031 subsection (d) also requires the Bureau to inform other relevant licensing authorities when a licensee's local license, permit, or other authorization is revoked.

Without this requirement, the Bureau may not be aware of these events. The Bureau would only potentially learn of these events at time of renewal. The enumerated events are relevant and material to the on-going qualifications of the applicant.

Proposed subsections (a) and (b) require a licensee to notify the Bureau within 48 hours following a conviction of criminal activity or following the rendering of a civil penalty or judgment against a licensee. 48 hours was determined to be time enough to provide notification to the Bureau, while allowing the Bureau to receive prompt notification. It is necessary for the Bureau to be notified of a criminal conviction or a civil penalty or judgment of a licensee because the conviction, civil penalty, or judgment may impair the licensee's ability to hold a license from the Bureau. Notice of the event is the first necessary step in order for the Bureau to investigate whether or not disciplinary action should be taken. Requiring a licensee to notify the Bureau of a criminal conviction or the rendering of a civil penalty or judgment will ensure that the Bureau is able to properly enforce the provisions of the regulations and the Act.

Proposed subsection (c) requires a licensee to notify the Bureau within 48 hours following an administrative order or civil judgement for violations of labor standards against the licensee or any owner in their individual capacity. 48 hours was determined to be time enough to provide notification to the Bureau, while allowing the Bureau to receive prompt notification. It is necessary for the Bureau to be notified of such an event occurring because a violation of labor standards may indicate that the licensee is not fit to hold a license from the Bureau. Notice of the event is the first necessary step in order for the Bureau to investigate whether or not disciplinary action should be taken. Requiring a licensee to notify the Bureau of a violation of labor standards will ensure that the Bureau is able to properly enforce the provisions of the regulations and the Act. The proposed subsection also specifies that the notification must be in writing and must include the date of the order, the name of the agency issuing the order, and a description of the administrative penalty or judgement.

Proposed subsection (d) requires a licensee to notify the Bureau within 48 hours following the revocation of a licensee's local license, permit, or other authorization. 48 hours was determined to be time enough to provide notification to the Bureau, while allowing the Bureau to receive prompt notification. It is necessary for the Bureau to require a licensee to report the revocation of his or her local license, permit, or other authorization to the Bureau, so the Bureau can inform other relevant licensing authorities as required in statute. This will ensure that the Bureau and other licensing authorities are informed in a timely fashion of the status of their licensees. This will also allow the Bureau and other licensing authorities to conduct their own investigations and take disciplinary action if necessary.

§ 5036. Notification of Theft, Loss, and Criminal Activity

This section describes the licensee's notification requirements for specific events, including diversion, theft, loss, or any other criminal activity pertaining to the operations of the licensee. Without this requirement, the Bureau may not be aware of these events. The Bureau would only potentially learn of these events at time of renewal. The enumerated events are relevant and material to the on-going qualifications of the applicant.

Proposed subsection (a) requires a licensee to notify the Bureau within 24 hours. Proposed subsection (b) requires notice to be provided in writing and include the date and time of occurrence of the theft, loss, or criminal activity, the name of the local law enforcement agency that was notified, and a description of the incident. It is necessary for the Bureau to be notified of the enumerated activities because they may impair the licensee's ability to hold a license from the Bureau. Notice of the event is the first necessary step in order for the Bureau to investigate whether or not disciplinary action should be taken. Requiring a licensee to notify the Bureau will ensure that the Bureau is able to properly enforce the provisions of the regulations and the Act. 24 hours was determined to be necessary so that the Bureau was promptly advised of the situation and could take swift action if deemed necessary.

§ 5037. Record Retention

Sections 26160 through 26162.5 of the Business and Professions Code provide the general framework for recordkeeping by licensed commercial cannabis entities. The purpose of this proposed section is to further define what must be stored and maintained as a record, to

clarify how and how long records must be stored, to clarify that a licensee may contract with a third party to provide custodial or management services of the records, and to clarify that all records related to commercial cannabis activity are subject to inspection by the Bureau.

Business and Professions Code section 26160 requires a licensee to keep accurate records of commercial cannabis activity. However, this section does not define what types of records of commercial cannabis activity must be maintained. Proposed subsection (a) clarifies the types of records that a licensee must maintain. The purpose of this proposed subsection (a) is to define what must be stored and maintained as a record. Specifically, proposed subdivisions (a)(1) through (a)(9) include financial records; personnel records; training records; contracts with other licensees; local authorizations; security records; records relating to the composting or destruction of cannabis goods; documentation for data or information entered into the track and trace system; and all other documents prepared or executed by an owner or his employees in connection with the licensed commercial cannabis business as records which must be maintained by a licensee. This makes specific the type of documents that must be kept; therefore, providing clarity to licensees. The requirement that these be maintained as records will aid the Bureau in enforcing these regulations, conducting investigations, and in preventing diversion and other illegal activity as these records provide information related to licensed cannabis activity and the requirements for cannabis businesses.

Subsection (b) is necessary to assure that records are consistently prepared and retained by all Bureau licensees. Specifically, this subsection assures that all records are legible and are protected from dust, moisture, contamination, or any other condition that would render the records illegible upon review by Bureau staff.

The purpose of proposed subsections (c), (d), and (e) is to require that records be kept in a manner that allows them to be immediately produced for the Bureau at the licensed premises for inspection. This will ensure that the Bureau is able to conduct timely inspections when needed and prevent destruction of records requested by the Bureau. These subsections also assure that the Bureau can effectively enforce its regulations and conduct thorough investigations.

§ 5038. Disaster Relief

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, 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 the Act, and the regulation of commercial cannabis activity. Notice of commercial cannabis activity that may be in conflict with the Act 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. The definition of disaster is consistent with the state or local jurisdiction declaring a state of emergency pursuant to the Government Code; therefore consistent with existing law.

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.

§ 5039. License Posting Requirement

This proposed section requires the licensee to display their current state license where the Bureau, other state agencies, local agencies, and prospective customers can easily see it, which will allow any agency representative on a routine inspection to readily determine validity of a license. This protocol is widely utilized by licensing agencies for many varieties of licenses. The requirement to post the license will allow officials and the public to easily confirm if the premises is properly licensed, thus, helping to prevent unlicensed activities.

§ 5040. Advertising Placement

Business and Professions Code section 26151(b) provides that any “advertising or marketing placed in broadcast, cable, radio, print, and digital communications shall only be displayed where at least 71.6 percent of the audience is reasonably expected to be 21 years of age or older, as determined by reliable, up-to-date audience composition data.” For convenience and clarity purposes, subdivision (a) of this section restates the requirements of the Act and provides clarification on how licensees may assure their advertising and marketing is tailored to appropriate audiences and not children. Specifically, subsection (a) provides that licensees must be able to demonstrate that at least 71.6 percent of the audience

viewing the advertising or marketing is reasonably expected to be 21 years of age or older. Moreover, subsection (a) prohibits the use of minors or their images in advertisements and prohibits the use of promotions or marketing tools which may be attractive to children to help prevent minor's access to cannabis goods as well as their being attracted to cannabis goods. Advertisement of free goods are prohibited as the Act does not allow for free goods as part of business promotion.

Proposed subsection (b) is necessary to assure that a licensee's marketing and advertising is affixed to a building or permanent structure. Requiring advertising to be affixed to a building or permanent structure assures that advertising or marketing remains placed in locations where the audience viewing the advertising or marketing is reasonably expected to be 21 years of age or older.

Recognizing that "reliable up-to-date audience composition data" is not defined by the Act, subsection (c) is necessary to provide clarity to licensees on how they may demonstrate that at least 71.6 percent of the audience viewing the advertising or marketing is reasonably expected to be 21 years of age or older. Because the audience viewing advertising or marketing may be transitory and may not necessarily correspond to census or population estimates, it is integral for licensees to demonstrate that audiences actually viewing their marketing tools are of age.

Proposed subsections (d) and (e) provide further clarity on how the Bureau will enforce the identified requirements. Subsection (d) provides that upon request, licensees must provide the Bureau with audience composition data supporting the placement of advertising; requiring a licensee to provide audience composition data to the Bureau will ensure that the Bureau is able to properly enforce the regulations and the Act. Subsection (e) provides necessary clarification to licensees regarding the consequences of not supplying audience composition data in support of the advertising or marketing.

It is common for licensees to contract with other agents, representatives, or consultants for advertising and marketing services. Accordingly, subsection (f) is necessary for the Bureau to assure that all advertising and marketing done on behalf of a licensee satisfies the provisions of the Act and its implementing regulations. Specifically, this subsection clarifies to licensees that any act, omission, or failure of their advertising agent, representative, or contractor, shall be deemed an act, omission, or failure of the licensee. This will avoid situations in which licensees attempt to avoid responsibility for violations of the Act or regulations by having another party advertise or market on their behalf.

§ 5041. Age Confirmation in Advertising

Section 26151, subdivision (c) of the Business and Professions Code provides that any "advertising or marketing involving direct, individualized communication or dialogue controlled by the licensee shall utilize a method of age affirmation to verify that the recipient is 21 years of age or older before engaging in that communication or dialogue controlled by the licensee." This section is intended to provide clarity on this statutory

requirement. Specifically, proposed subsection (a) restates the requirements of Business and Professions Code 26151(c), for the ease and convenience of licensees.

Section 26151 (c) does not define what direct, individualized communication or dialogue is. Accordingly, subdivision (b) of this section is necessary to provide added clarity on what forms of communication must utilize age verification methods. Specifically, subdivision (b) provides that direct, individualized communication or dialogue occurs through any form of communication, including in-person, telephone, physical mail, or electronic mail. These methods allow for communication to be focused on a particular individual; thus, allow for direct communication.

Subdivision (c) is necessary to address situations where a recipient has already gone through age verification. Specifically, subsection (c) does not require age verification if the licensee can verify that the recipient has already undergone a method of age affirmation, and the communication is reasonably certain to only reach the intended recipient.

Licensees may develop mailing lists for targeted marketing or advertising communications. Accordingly, subsection (d) is necessary to clarify age verification is required prior to adding a potential customer to a mailing list or subscription to received direct communications controlled by the licensee.

§ 5042. Limited-Access Areas

Business and Professions Code section 26070, subdivision (j) requires that retailers, microbusinesses and nonprofits implement certain security measures, including establishing limited-access areas accessible only to authorized personnel. The proposed section specifies who may access the limited-access areas and what is required for tracking access to the limited-access areas. The expected benefit of these subsections is that it will prevent unauthorized individuals from entering the limited-access area which will result in a decrease in the risk of theft and other crimes.

Proposed section 5042 specifies the requirements for limited-access areas. Proposed subsection (a) specifies that any individual who is not an employee, or an authorized individual, must be escorted by the licensee or at least one employee, when in the limited-access areas of the licensed premises. This is necessary to ensure that anyone who has access to the limited-access areas has been given permission by the licensee and is accompanied by someone authorized to enter the limited-access areas to prevent theft or other acts.

Proposed subsection (b) states that for purposes of this section, the term “authorized individuals” includes individuals employed by the licensee as well as any outside vendors, contractors, or other individuals conducting business that requires access to the limited-access areas. This is necessary to specify who a licensee may authorize to enter the limited-access areas and ensuring these persons have a legitimate business reason to be in the area.

Proposed subsection (c) specifies that all individuals who are not employees shall be escorted by an employee of the licensee at all times while within the limited-access areas.

This is necessary to preserve the safety and security of the licensed premises by ensuring that authorized individuals who enter the limited-access area are supervised. For various reasons, individuals who are not employees will be required to enter the limited-access area. For example, a plumber or electrician may need to enter to make repairs. This section addresses the increased risk of theft or other crime if these non-employee individuals are not supervised while in the limited-access area. Additionally, this subsection ensures that the licensee is aware of what occurs in the limited-access area at all times. This will result in a reduction of the risk of theft or other crimes.

Proposed subsection (d) would require the licensee to maintain a record of all authorized individuals who are not employees of the licensee that enter the limited-access area. The purpose of this subsection is to protect the safety and security of the licensed facility.

Because the limited-access area is where the licensee's inventory of cannabis goods and possibly compensation is kept, it is important to keep a record of who enters the area. The expected benefit of this section is that all licensed dispensaries will keep a log of all non-licensee employees who enter the limited access area. This log can be used during the course of an investigation by the Bureau, the licensee, or law enforcement.

Proposed subsection (e) provides that a licensee shall not receive consideration for permitting an individual to enter the limited-access areas. The purpose of this subsection is to protect the safety and security of the licensed facility by preventing licensees from having access as payment. Access to the area should be limited to those individuals who require access for the operation of the licensee. A licensee that allows an unauthorized individual into the limited-access area for any reason is increasing the risk of theft or other crime.

Proposed subsection (f) would require that entrances to all limited-access areas have a solid door with a commercial-grade, nonresidential door lock. Further, the subsection would require that the door remain closed when not in use during regular business hours. This subsection is necessary to ensure that limited-access areas are secure. In order to reduce the risk of theft, the limited-access area must be difficult for a nonemployee to enter. During inspections of licensed premises, the Bureau has found that some limited-access areas had a curtain door, or other similar unsecure door. These unsecure doors increase the likelihood of unauthorized access and risk of theft or other crimes. Requiring a solid door with a commercial-grade lock ensures that the limited-access area is secure and can only be accessed by authorized individuals.

§ 5043. Licensee Employee Badge Requirement

Proposed section 5043 requires all employees, agents and other representatives of the licensee to display an identification badge while engaging in commercial cannabis activity. The employee badge must meet specific requirements, such as being laminated, including the licensee's DBA and the employee's name, as well as a colored photograph of the employee or agent, which is within a certain dimension.

This section is necessary to minimize the risk of illegal or criminal activity on licensed premises, by accounting for individuals who engage in commercial cannabis activity. It

also serves to provide the customers and members of the public with confidence and assurance when purchasing cannabis goods, and a mechanism to help provide for accountability. The information on the badge is necessary to identify the employee and his or her employer. The dimensions of the photo are large enough to compare to a person and still fit on an identification card.

§ 5044. Video Surveillance System

Proposed section 5044 requires each licensed premises to maintain a video surveillance system (VSS) that meets specific requirements. Proposed subdivision (a) requires a VSS to have at a minimum, camera resolution of 1280 x 720 pixels. This resolution allows for pictures that are clear enough to show detail while balancing costs. Proposed subdivision (b) requires the storage device or cameras to be transmission control protocol capable of being accessed through the internet which is necessary if storage of video footage is cloud based. Proposed subdivisions (c) and (d) require the VSS to effectively and clearly record images of the area and activities under surveillance, through permanently mounted and fixed locations that records within 20 feet of all points of entry and exit on the licensed premises, which is necessary to ensure activities will be captured. Proposed subdivision (e) would specify the areas of the premises that must be recorded including, areas where cannabis goods are weighed, packed, stored, loaded and unloaded for transportation, limited-access areas, security rooms, areas storing a VSS storage device, and entrances and exits to the premises. This is necessary to prevent diversion and theft because any act or movement of cannabis goods will be recorded.

Proposed subsection (f) would specify that retailers and microbusinesses must also record point-of-sale areas and areas where cannabis goods are displayed for sale. Proposed subsection (f) would also clarify that camera placement must allow for the recording of the facial features of any person purchasing or selling cannabis goods or any person in the retail area, with sufficient clarity to determine identity. This is necessary so that when the Bureau or law enforcement is investigating complaints of underage customers, they can review the footage to determine who the employee was that may have made a sale to an underage customer and determine if the customer appears to be underage. Further, commercial cannabis is a cash-intensive industry which leads to a higher potential for robbery and other criminal acts. This subsection is necessary to ensure that the Bureau and law enforcement can easily identify the perpetrators of any criminal act.

Proposed subsection (g) would require that the cameras record for 24 hours per day at a minimum of 15 frames per second. This requirement is necessary to ensure that at any time of day the premises is under video surveillance. This is necessary because criminal activity may occur at any time and is more likely to occur when the business is closed. This requirement helps to ensure that any perpetrators of any criminal act are identified. The Bureau reviewed various amounts of frames per second and determined that 15 frames per second provided the oversight and detail that the Bureau, law enforcement, and the licensee need to clearly view and identify any unauthorized or criminal activity. The Bureau selected the least frames per second that would meet the need to clearly identify all

activities and persons on the licensed premises. The Bureau chose not to require more frames per second because those systems cost more.

Proposed subsections (h)-(k) would clarify that the recordings must be stored in a secured manner to protect them from tampering or theft, that they must be kept for 90 days, that the recordings are subject to inspection by the Bureau, must be maintained in a manner that allows the Bureau to view and obtain copies, and that the recorded images clearly and accurately display the date and time. This is necessary because an unlawful act or violation of the regulations may not be discovered until days or weeks later. This ensures that a licensee has recordings dating back to when an event may have occurred such as theft or diversion of cannabis goods. This also allows the Bureau the opportunity to review incidents that occurred days or weeks prior, while balancing the cost of maintaining this video.

Proposed subsection (l) requires the VSS be equipped with a failure notification system that provides notification to the licensee of any interruption or failure of the VSS. This is necessary to ensure that a licensee is made aware of a failure in the system right away and can resolve the issue timely.

Proposed subsection (m) specifies that if there are multiple premises within the same building that the licensees may share a VSS if certain conditions are met including that they provide an explanation of how the VSS will be shared in their operating procedures that are submitted with the application, that each licensee have immediate access to the VSS, and that each licensee will be held responsible and subject to discipline for any violations. This is necessary based on feedback that allowing this would result in a cost savings for licensees. By requiring all licensees to be responsible, the Bureau will be able to avoid the licensees pointing fingers at one another when a violation occurs.

This section is necessary to ensure the safety of the individuals engaging in commercial cannabis activity, which is a cash-intensive industry, and more prone to safety risks. The benefit of this section is that a VSS will not only deter potential criminal and illegal activities, but will also help the licensee, the Bureau, and law enforcement when reviewing illegal or criminal activities that have occurred.

§ 5045. Security Personnel

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. Public comments received initially from commercial cannabis businesses indicated that many in the cannabis market had already 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.

Proposed subsection (a) would specify that retailers and microbusinesses engaged in retail shall hire or contract with security personnel that have been licensed by the Bureau of Security and Investigative Services and are at least 21 years of age. This is necessary to ensure that security personnel are licensed as required by law and to ensure that no person under the age of 21 has access to cannabis goods.

Proposed subsection (b) provides an exception to subsection (a) and exempts non-storefront retailers from the security requirement. This is necessary because non-storefront retailers sale cannabis goods through delivery only. Therefore, there is no concern with the public having access to the premises and thus reduces the likelihood of criminal activity. This also benefits the licensees by allowing them to save on costs.

Proposed subsection (c) specifies that if multiple premises are contained within the same building, security personnel may be shared if the licensees include in their security operating procedure how the security personnel will be shared and specifies that each licensee shall be held responsible and subject to discipline for violations. This is necessary due to feedback from licensees related to costs. The Bureau determined that this was acceptable as sharing security personnel allows licensees to save on costs by sharing the expense of security personnel.

§ 5046. Locks

Proposed Section 5046 requires that licensees use nonresidential commercial-grade locks on their licensed premises, for limited-access areas and all points of entry and exit.

This section is necessary to ensure standardized security measures, and the use of non-residential commercial grade locks will ensure a more secure premise. Heightened security is necessary because cannabis businesses have high value inventory and financial resources.

§ 5047. Alarm System

This section requires each licensee to keep and maintain an alarm system as defined in the Business and Professions Code section 7590.1, subsection (n). The MAUCRSA mandates the Bureau craft regulations that ensure a safe and secure operation of the commercial cannabis market. Current law permits the use of alarm systems but does not clarify the type or quality. This section is necessary to clarify for licensees the type and quality of alarm systems permitted for use. Alarm systems will prevent theft and help ensure public safety.

The Bureau determined that an alarm system must be provided by a company authorized to do so by law. Proposed subsection (d) would clarify that when multiple premises are contained within the same building, the premises may share a single alarm system.

This section is necessary because, as with VSS and security personnel, the Bureau determined that it was acceptable for sharing by licensees in the same building as long as they provided an explanation of how it is shared in their security operating procedure, that each licensee have access to information related to the system in order to provide it to the

Bureau, and that each licensee will be held responsible and subject to discipline for any violations. This provision also benefits the licensees by allowing them to save on costs by sharing the expense of the alarm system.

§ 5048. Track and Trace System

Proposed section 5048 provides the overview of the track and trace system and how licensees are to manage and use the track and trace systems for commercial cannabis activity. Subsection (a) requires the licensee to create and maintain an active and functional account within the track and trace system prior to engaging in any commercial cannabis activity. Subsections (b) and (c) provide that one individual owner is to be designated as the track and trace system account manager for each license, and such owner can authorize additional owners and employees to access and use the track and trace system, through a unique log-on. Subsection (d) requires the account manager to maintain a complete list of all track and trace system users. Subsection (e) requires licensees to timely address compliance notifications from the track and trace system, so that the cannabis goods can be accurately tracked and traced. Subsection (f) provides that the licensee is ultimately responsible for the acts of its owners and employees for all activities involving the track and trace system.

Business and Professions Code section 26067 requires CDFA, in consultation with the Bureau, to establish a track and trace system for the movement of cannabis goods throughout the distribution chain. These proposed regulations are necessary to implement statutory law and provide guidance on the implementation and proper use of the track and trace system, so that cannabis goods can be accurately tracked and traced. Subsections (b), (c), (d), and (e) are necessary to ensure accountability of the user and the integrity of the data entered into the track and trace system. It is also necessary to ensure compliance with the track and trace system, and an ability to oversee and enforce the track and trace provisions by licensing authorities. Subsection (f) will ensure that the licensee's track and trace system is monitored for any deficiencies that would derail the ability to track the cannabis goods from seed to sale, and is necessary to comply with and implement Business and Professions Code section 26067, subdivision (b)(2)(A), which requires the track and trace system to flag irregularities for all licensing authorities to investigate.

§ 5049. Track and Trace Reporting

Proposed section 5049, subsections (a) and (b) provide what specific information and data of each commercial cannabis activity, must be entered into the track and trace system, as required under Business and Professions Code section 26067. Subsections (c) and (d) provides the timeframe for when all required information must be entered into the system, generally within 24 hours of occurrence. It also specifies that licensees must correct all known errors immediately.

This section is necessary to implement Business and Professions Code sections 26067 and 26069, and clarify the statutory provisions for track and trace system reporting. It provides licensees guidance as to what specific information needs to be entered into the track and trace system, so there is consistent and complete data entered by the licensees as the cannabis good

moves along the distribution chain, and ultimately to the consumers. CDFA requires all licensed cultivators to assign a unique identifier (UID) to each cannabis seed and plant, so it can be traced throughout the distribution chain. Subsection (c), which requires the licensee to enter specific information into the track and trace system within 24 hours, and to immediately correct any known errors, which is necessary to ensure the integrity and accuracy of the information, as the track and trace system is used as a real-time tracking system for both licensees and licensing authorities. Proposed subsection (d) specifies that licensees shall only enter complete and accurate information in the track and trace system and known errors shall be corrected immediately upon discovery which, is necessary to ensure that the track and trace system has up to date reliable information. This section is also necessary for recall purposes, to track the cannabis good to the source of contamination or adulteration, and to timely access and remediate the risks and dangers to public health and safety, and investigate processes to determine the reasons for the recall.

§ 5050. Loss of Access

Proposed section 5050, subsections (a) and (b) require a licensee who has lost access to the track and trace system to prepare and maintain comprehensive records detailing the commercial cannabis activities conducted during loss, and to notify the Bureau of the loss of access. Subsection (c) requires a licensee to update the track and trace system once it is restored, within a specified timeframe. Subsection (d) prohibits a licensee from transporting, transferring, or delivery any cannabis goods until access is restored, and necessary information updated in the system.

As an integral system to monitor and enforce cannabis activity for public health and safety, loss of access to the track and trace system could negatively impact the ability to protect against unlawful inversion and diversion. Proposed section 5050 is necessary in providing guidance and clarification on the duties and responsibilities of licensees when they lose access to the track and trace system, and to ensure that cannabis is not easily diverted in the supply chain. The most efficient and direct way to accomplish this is to ensure that all required information is entered into the track and trace system, and when access to the system is lost, to restrict or limit the commercial cannabis activities so cannabis goods can be accurately and consistently tracked.

§ 5051. Track and Trace System Reconciliation

Proposed section 5051 requires the licensee to reconcile cannabis goods inventory within the track and trace system at least once every 14 calendar days, and to report any discrepancies to the Bureau within the time specified. Business and Professions Code section 26068 provides that the track and trace program shall include a system with data points for different stages of commercial activity, including inventory. The Bureau selected 14 calendar days to reconcile cannabis goods inventory within the track and trace system because that is the same time period provided in proposed sections 5309 and 5424 for distributors and retailers to conduct inventory reconciliation. By requiring the track and trace reconciliation to be done within the same time period, distributors and retailers can conduct their inventory reconciliation and track and trace reconciliation at the same time. Proposed section 5051 is

necessary to ensure that the track and trace program can be effectively used and carried out, by requiring licensees to perform inventory checks. This provides accountability and aligns the efficacy of the track and trace system with the practices of the licensee in ensuring that cannabis goods are properly tracked and monitored.

§ 5052. Temporary Licenses; Licensees in Operation at Time of Licensure

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 within one month which allows a licensee with a large inventory a reasonable time to perform this task. 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.

§ 5052.1. Acceptance of Shipments

Proposed section 5052.1 provides that shipments of cannabis goods must be accepted or rejected in whole. Subsection (b) clarifies that if the shipment contains cannabis goods that were not ordered by the receiving licensee, that part of the shipment may be rejected, while the remaining shipment containing cannabis goods that were ordered, may be accepted. This section is necessary to provide clarification and guidance on the process for accepting shipments of cannabis goods, so that cannabis goods can be accurately tracked and traced, and licensees can adhere to the requirements on returns of cannabis goods between licensees. This section will also help to prevent the diversion of cannabis goods into the illegal market, by limiting the transfer of cannabis goods when ownership and possession may be ambiguous during the distribution chain.

§ 5053. Returns Between Licensees

MAUCRSA defines the terms “sell,” “sale,” and “to sell,” to include transactions where title of cannabis or cannabis products are transferred from one person to another, and where

delivery is made pursuant to an order for the purchase of such goods, but does not include the return of cannabis goods between licensees. Proposed section 5053 provides that licensees may not return cannabis goods purchased from other licensees, unless it is a manufactured cannabis good that is defective, and only then can the return be made in exchange for a non-defective version of the same type of cannabis good, or of equal value.

This section is necessary to ensure that cannabis goods maintain integrity in the marketplace and to limit cannabis goods from being shuffled around and hard to track. This section is also aligned with the regulations pertaining to cultivation of cannabis, and the prohibition of licensees with a cultivation license from accepting returns of cannabis plants or nonmanufactured cannabis products after transferring possession to another licensee and testing is performed.

§ 5054. Destruction of Cannabis Goods Prior to Disposal

Business and Professions Code section 26104 requires the Bureau to develop procedures requiring the destruction of cannabis goods whose testing samples indicate noncompliance with health and safety standards. Proposed subsection (a) of section 5054, applying to all Bureau licensees, provides that cannabis goods cannot be disposed of unless, they are disposed as cannabis waste. Proposed subsection (b) clarifies how cannabis goods can be disposed of as cannabis waste, which is by removing the cannabis good from its packaging and rendering it unrecognizable and unusable.

Proposed section 5054 is necessary to ensure that cannabis goods are properly rendered unusable and unrecognizable prior to disposal so there is delineation and easy and clear identification between cannabis waste, and cannabis goods that are fit for sale and consumption. This also ensures that cannabis goods that are deemed unfit for sale and consumption are not diverted back into the supply chain or the cannabis market.

§ 5055. Cannabis Waste Management

Proposed section 5055 specifies how licensees can handle and dispose of cannabis waste, which is defined under proposed section 5000, subsection (d), as waste that is not hazardous waste (as defined in Public Resources Code section 40141), is organic waste (as defined in Public Resources Code section 42649.8), and containing cannabis and made unusable and unrecognizable. This section establishes the procedures and practices for cannabis waste management to ensure that cannabis goods are properly disposed of as cannabis waste, and not accessible by unauthorized individuals or children. Proposed section 5055, subsections (a) and (b), prohibit licensees from selling cannabis waste, and require compliance with waste management laws under Division 30 of the Public Resources Code. Proposed subsection (c) provides clarification on the meaning of certain terms used in this section, including, third-party waste hauler, solid waste facility, and a secured waste receptacle. Proposed subsection (d) provides that a licensee shall dispose of cannabis waste on the licensed premises, in a secured waste receptacle or in a secured area, until it can be collected and processed at a solid waste facility. Proposed subsection (e) specifies that a licensee must have a cannabis waste management plan in place, with one of three ways to dispose of

cannabis waste, either by composting, or hauling to a waste facility by the licensee or through a third-party. Composting is to be done in compliance with California Code of Regulations, title 14, chapter 3.1 (commencing with Section 17850), while if cannabis waste is disposed of through a waste hauler, there are specific requirements for a local agency or local agency permitted waste hauler, or if done by the licensee, pursuant to proposed subsection (e)(2).

Proposed section 5055 is necessary to ensure that cannabis goods are properly disposed of, as it provides specific procedures and practices that are aligned with existing waste management laws under the Public Resources Code. It ensures that there is accountability and oversight over the cannabis waste management process, so that cannabis does not become improperly diverted, accessed, or sold in the process of rendering it as waste.

§ 5300. Distribution Activities

This proposed section prohibits the distribution or storage of non-cannabis goods or non-cannabis accessories with the exception of licensee branded merchandise or promotional materials.

This section is necessary to clearly delineate what activities 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 at licensed premises. A distributor licensed by the Bureau may only engage in the activity it is licensed for; the transport and storage of cannabis goods. To allow transport and storage of non-cannabis goods would degrade the ability of the Bureau to enforce and administer the provisions of MAUCRSA and its implementing regulations. This will ensure integrity of the cannabis goods and cannabis activity. Based on feedback from licensees, the Bureau determined that allowing branded merchandise and promotional materials was related to cannabis activity and therefore allows the distribution of these items.

§ 5301. Storage Services

This proposed section allows for a distributor to store cannabis goods for another licensee, unrelated to the quality assurance and laboratory testing processes. Proposed subsection (a) allows for flexibility between cannabis business license types and is necessary to allow for efficiency in the distribution chain. This will meet the specific needs of businesses requiring additional storage due to their own premises constraints, without requiring them to disrupt their business operations or expend large overhead costs in changing their premises or structural fixtures. Distribution facilities must house cannabis goods batches for testing, therefore, are equipped to provide appropriate storage needed by other licensees.

Proposed subsection (b) clarifies that a distributor may provide storage services only for items that the distributor is authorized to store under section 5300 of this division to ensure cannabis activity is consistent with license privileges.

Proposed subsection (c) prohibits a distributor from storing live plants on their licensed premises. This proposed subsection is necessary to clarify the limitations of the storage service that a distributor may provide. A distributor who stores live cannabis plants on their

premises is essentially engaging in cultivation because it is impossible to stop live plants from continuing to grow. Since distributors are not authorized to engage in cultivation, distributors should be prohibited from storing live plants.

§ 5302. Storage of Batches for Testing

All cannabis goods must pass through a licensed distributor, prior to retail sale. Specifically, pursuant to MAUCRSA, under Business and Professions Code section 26100 et seq., licensed distributors are responsible for quality assurance review, as well as ensuring laboratory testing of cannabis goods, and are required to store cannabis batches on their licensed premises before testing and continuously after it is determined whether the cannabis batch passes or fails testing.

Proposed subsection (a) requires distributors to store cannabis goods batches in such a manner that the batches are kept separately and distinctly from other cannabis goods batches at all times. Proposed subsection (b) specifies ways in which this must be done, including labeling each container holding cannabis goods with relevant information to determine the origination of the batch; descriptions to easily identify the batch; date and time of entry into the storage area; and unique identifiers and batch numbers. To ensure the traceability of cannabis batches, it is imperative that the distinct batches are readily identifiable while in storage. It is also necessary to ensure that cannabis batches are not cross-contaminated, and the testing process preserved. This can be achieved through this proposed regulation in maintaining identification and separation of cannabis goods batches in storage. This section ensures that batches are easily identified, so that the appropriate amount of samples are taken from the correct batch.

§ 5303. Packaging and Labeling

Proposed section 5303 prohibits a distributor from packaging, re-packaging, labeling, or re-labeling cannabis products, with certain exceptions. Subsection (a) allows distributors to package and label cannabis, including pre-rolls, so that, after a batch has gone through laboratory testing, the cannabis need not return to the cultivator for packaging and labeling, as prohibited by the Department of Food and Agriculture's regulations. Subsection (b) clarifies that if a distributor also holds a manufacturing license, it is not prohibited from packaging and labeling its own manufactured cannabis products on its manufacturing licensed premises.

Proposed subsection (c) allows the distributor to re-label packages where the cannabinoid or terpenoid levels are determined to be incorrect, but within limits for sale, during laboratory testing on a manufactured product. This provision would eliminate the need to transfer possession of cannabis products back to the originating manufacturer, thus minimizing the unrestricted movement of cannabis products through the supply chain. The distributor must provide the manufacturer with the certificate of analysis showing the label claim and the actual levels found in testing.

Along with storage and destruction, the ability of a distributor to package and label cannabis goods will allow for more efficient and streamlined movement of cannabis goods through the distribution chain, which is necessary to minimize the disruption to the commercial cannabis enterprise. Disruptions to the movement of cannabis goods through

the supply chain will increase risks of diversion, as the cannabis goods will be exposed to a larger number of entities and persons before ultimately reaching the retailer and end-user. This section ensures that the risk of diversion is decreased, while also ensuring the risk of cannabis goods being contaminated after laboratory testing is decreased by limiting the ability to go back through the supply chain for relabeling. Additionally, providing the information to a manufacturer if relabeling occurs, allows the California Department of Public Health to monitor if a manufacturer's labels consistently do not match testing results.

§ 5303.1. Net Weight of Dried Flower

Proposed section 5303.1 clarifies that the net weight of any dried flower package is considered accurate when the actual weight is within 2.5% of the labeled weight. The purpose of this proposed section is to clarify and provide guidance as to when a dried flower package may be inaccurately labeled, requiring any re-labeling. Recognizing that dried flower may lose or acquire moisture over time, which impacts the weight of the dried flower, this proposed section is necessary to account for how much the weight may change.

§ 5304. Testing Arrangements

Proposed section 5304 specifies that after a distributor takes possession of a cannabis goods batch, the distributor shall arrange for a laboratory employee to travel to the distributor's premises to select a representative sample for testing. This section reiterates and clarifies Business and Professions Code section 26110, subdivision (d), which requires the distributor to arrange for a testing laboratory to obtain a representative sample of each cannabis batch at the distributor's licensed premises. This section is necessary to carry out the statutory requirement that all cannabis batches be subject to quality assurance and testing. It specifies when distributors are responsible to make such arrangements, which is after taking physical possession of cannabis goods. It also specifies that laboratory employees are responsible for obtaining the sample, as required under Business and Professions Code section 26104, subdivision (b)(4). This clarification is beneficial to let licensees know what their specific responsibilities are for testing arrangements, so there is no confusion as to who needs to initiate testing arrangements, or who is responsible for collecting a sample.

§ 5305. Testing Sample

Laboratory testing is an integral part of quality assurance for cannabis goods, and sample collection is key to performing a scientifically valid analysis of cannabis products. Without proper sampling, laboratory test results would likely be inaccurate, rendering the testing moot.

Proposed subsection (a) requires the distributor to ensure the batch size the sample is taken from meets the appropriate sampling requirements. The batch size must meet the requirement, so the sampling is a representative sample of the cannabis to be tested. These requirements will also ensure fair and consistent standards for testing among all licenses, by limiting the potential for results to be contaminated or corrupted.

Proposed subsection (b) requires the distributor, or its employee, to be physically present to witness the laboratory employee obtain the sample. This requirement ensures that the cannabis collected for testing is obtained from throughout the batch, thereby limiting the potential for samples to be collected from one centralized area of the batch. Collecting samples from one centralized area of the batch may not be representative of the entire batch; sampling different areas of the batch ensures the testing is fair, accurate, and representative.

Proposed subsection (c) requires that the act of sampling be video recorded with the batch number stated at the beginning of the video, verbally or through signage, and a time and date indication visible on the recorded footage. Per this proposed subsection, distributors must maintain the recordings for 90 days. A 90-day period was identified to ensure that the Bureau has sufficient time to review the sampling process, if there are any complaints or allegations of improper sampling and testing.

Requirements to address the situations of nonexistent or improper sampling, intentional tampering with cannabis during sampling, and any disputes between licensees that may arise regarding sampling procedures are addressed in proposed subsection (d) by requiring the distributor and the laboratory employee sign and date the chain of custody form attesting the sampling has been completed. Subsection (e) prohibits the distributor from assisting the laboratory employee or touching the cannabis goods during the sampling process. These requirements are necessary to preserve the integrity of the sampling and testing process, as one of the more integral parts of quality assurance. These provisions, which also specify the roles and responsibilities of the licensees, are necessary to provide accountability for proper testing, which ultimately, ensures that cannabis goods are safe for consumption by the public.

§ 5306. Laboratory Testing Results

This proposed section specifies the process for when a cannabis goods batch passes or fails the state-mandated laboratory testing, clarifying Business and Professions Code sections 26100 and 26110. Under proposed subsections (a) and (b), a batch passes if the samples analyzed by the testing laboratory meet the specifications set forth by regulation in Chapter 6 of this division, allowing the distributor to transport the cannabis goods to retailers. Conversely, as stated in proposed subsections (c) and (d), the batch fails testing if the samples analyzed by the laboratory do not meet the specifications set in regulation in Chapter 6, requiring the distributor to either relabel the cannabis goods if permissible; arrange for transportation of the cannabis product batch back to the manufacturer for remediation; or if the distributor is unable to do either, to destroy the failed batch.

This proposed section is necessary to carry out the requirement under MAUCRSA that all cannabis batches be subject to quality assurance review and testing, and specifies how cannabis goods that meet testing standards may be safely sold to consumers, and how cannabis goods that fail testing are to be handled and disposed of so that they are not illegally diverted, or exposed to children or other individuals. It further clarifies the requirement under Business and Professions Code section 26110, subdivision (c)(1), that all cannabis goods are stored on the distributor's premises until testing determines how the distributor may treat the cannabis goods. Finally, this section is necessary to ensure proper

destruction and disposal of failed cannabis goods batches, by which the distributor who has physical possession of the cannabis goods, and is in the best position to carry out.

§ 5307. Quality-Assurance Review

This proposed section clarifies the process by which distributors perform quality assurance reviews after receiving a certificate of analysis, either from a testing laboratory or another licensed distributor, and before transporting any cannabis goods to a retailer or microbusiness for sale, as required by MAUCRSA, pursuant to Business and Professions Code section 26110, subdivision (e).

Proposed subsection (a) would require that distributors ensure that the certificate of analysis received from the licensed testing laboratory corresponds to the batch currently being held by the distributor. This requirement is necessary to ensure that batches are not mistakenly identified, thereby limiting the potential for a batch that has failed a laboratory test to be erroneously transported to a retailer or microbusiness for sale to consumers. This subsection will also account for the potential for cannabis goods batches to be mistakenly identified, due to their similar appearance to each other.

Proposed subsection (b) requires the distributor to ensure that, prior to transport to one or more retailers, cannabis goods are accurately labeled with the cannabinoid content and contaminants that correspond to the certificate of analysis. Under proposed subsection (c), the distributor shall ensure the cannabis packaging is tamper evident and conforms to specifications required in law. This is necessary because it ensures conformity with Business and Professions Code section 26110, subdivision (e) by ensuring that cannabis goods are not delivered to a retailer or microbusiness unless its packaging and labeling conforms to MAUCRSA and its implementing regulations.

Proposed subsections (d) and (e) would require a distributor to verify that the weight or quantity of the batch matches that entered into the track-and-trace database, and that all events prior to receipt have been entered into the track and trace system. These subsections are necessary to carry out the provisions of the statute requiring quality assurance review of cannabis goods prior to final distribution to a retailer. They clarify the specific duties and obligations of the distributor for carrying out quality assurance review, such as checking weight and count and track and trace system reconciliation. Without clarity as to what steps need to be taken for quality assurance review, there will be no consistency in quality and integrity of the cannabis goods at retail, which is integral to consumer safety and protection.

§ 5308. Insurance Requirements

Business and Professions Code section 26070, subdivision (a)(2) requires a distributor to be bonded and insured at a minimum level determined by the Bureau. Proposed section 5308 implements and clarifies the statutory insurance provision, by establishing the insurance requirements for distributors. This proposed section was developed in consultation with the California Department of Insurance.

Proposed subsection (a) requires an applicant for a distributor license to provide a certificate of insurance showing the minimum amounts of commercial general liability coverage, which are established in proposed subsection (b) as an aggregate in an amount no

less than \$2,000,000 and in an amount no less than \$1,000,000 for each loss. Proposed subsection (c) provides the company criteria from which a distributor licensee must maintain the insurance, such as a non-admitted insurer meeting certain requirements, a compliant registered risk retention group, or an insurer qualified and duly authorized to do business in California. Proposed subsection (d) provides further criteria on insurer requirements, such as proof of capitalization, and proposed subsection (e) requires the distributor licensee to notify the Bureau within 10 days of any lapse in insurance.

This proposed section is necessary to implement the statutory requirement for insurance, and establishes the minimum amount that distributors must carry. Applicants will know what requirements they must meet in order to obtain a distributor license. The identified amount is standard for businesses operating in an industry that is considered to have a higher risk of losses. The ban of the cannabis at the federal level creates a cash-heavy industry that may be more susceptible to criminal activity. The identified minimum insurance coverage is an amount that factors in these increased security risks. The requirements of carrying insurance from insurance companies meeting certain criteria is to ensure a level of security and confidence in the insurer who will maintain the insurance and meet the terms of the coverage. This section ensures that distributors who will be storing and transporting large amounts of cannabis goods are insured. This requirement helps protect other licensees from loss of their cannabis goods if something were to happen to them while in the custody of the distributor. Notifying the Bureau of any lapse in insurance is necessary for the Bureau to ensure that licensees continue to be fit for licensure, and continue to meet the statutory requirements under MAUCRSA.

§ 5309. Inventory Reconciliation

Proposed subsection (a) would require a distributor to reconcile all inventories of cannabis goods at least once every 14 days. To clarify the inventory reconciliation process, proposed subsection (b) provides what information must be contained in the inventory log, including the name of the cultivator or manufacturer providing the cannabis goods, when it entered the storage area, unique identifiers, weight or quantity, and any expiration dates for the batch of cannabis goods. Proposed subsection (c) requires distributors to conduct full audits when there is a discrepancy between the inventory on-hand and the log, which accounts for differences in inventories beyond normal weight fluctuations from moisture addition or loss.

This proposed section is necessary to track batches that are stored at the distributor's premises and to minimize the diversion of cannabis goods. As all cannabis goods will pass through a distributor, it is important that there are processes in place for a distributor to account for those goods, and decrease the risk of diversion. Inventory reconciliation is one method for accountability, and once a distributor finds a discrepancy, an audit is necessary to determine the cause of the discrepancy and whether law enforcement or the Bureau needs to be notified, pursuant to proposed section 5034. Such audits need to be done periodically so that the cause of any discrepancy can be more easily determined, and any action to remediate diversion or unauthorized or illegal possession can be taken as soon as possible. The Bureau determined that 14 days was an appropriate time to require inventory reconciliation because it allows frequency to quickly identify a problem without being a burden on the licensee if such was required daily.

§ 5310. Records

Business and Professions Code section 26160 requires licensees to maintain accurate records of commercial cannabis activity, for at least seven years. This proposed section lists the records distributors would be required to keep, in addition to those records identified in proposed section 5037, which would be available under these regulations for the Bureau to examine and inspect. The records in proposed subsections (a)(1) through (11) are business records related to cannabis distribution activity, including laboratory-testing records, contracts with other licensees and vendors, warehouse receipts, vehicle and trailer ownership records, quality assurance records, cannabis goods destruction records, tax payments, transportation bills and shipping manifests, inventory logs and records, and records relating to branding, packaging, and labeling.

This section is necessary to implement and carry out the statutory requirement for retention of commercial cannabis records. This provides clarity and advises the distributor licensee of the records they must maintain, that may be specific to distribution activities, and are in addition to those records identified in proposed section 5037.

§ 5311. Requirements for the Transportation of Cannabis Goods

This proposed section is required to establish security and safety requirements during the transportation and distribution of cannabis goods by distributor licensees and their employees, as required under Business and Professions section 26070.

Proposed subsection (a) reiterates the requirements of Business and Professions Code section 26070, subdivision (c), “The driver of a vehicle transporting or transferring cannabis or cannabis products shall be directly employed by a licensee authorized to transport or transfer cannabis or cannabis products.” This subsection is necessary to clarify the driver requirements for transportation.

Proposed subsection (b) requires that the distributor complete the sales invoice or receipt prior to beginning the transportation. Additionally, distributors are only authorized to transport cannabis goods identified on the sales invoice or receipt prepared for that transport. The purpose of this proposed section is to ensure that the transportation of cannabis goods is properly documented. The invoice that is prepared prior to transportation will allow the receiving licensee to verify that the cannabis goods they are receiving are accurately reflected in the invoice. Additionally, in the event of a traffic stop by law enforcement, the invoice may be used to provide justification to law enforcement for the transportation of the cannabis goods found in the vehicle.

Proposed subsection (c) is stated as defined in the Business and Professions Code section 26070, subsection (d), “[A]ll vehicles transporting cannabis and cannabis products for hire shall be required to have a motor carrier permit pursuant to Chapter 2 (commencing with Section 34620) of Division 14.85 of the Vehicle Code.” This section is necessary to clarify the specific vehicle registration requirements for distributors engaging in transportation for hire.

Proposed subsection (d) clarifies prohibited modes of transportation, which includes transportation by aircraft, watercraft, drone, rail, human powered vehicle, and unmanned vehicles. With this section, the Bureau endeavors to make sure cannabis goods are secure and that licensees are abiding by all rules and regulations during transport. Prohibiting the specific modes of transportation is necessary to reduce the risk of loss or theft, and attempts to limit potential conflicts with federal law and regulation. Additionally, enforcement of transportation by air, watercraft or drones, which often involve compliance with federal laws and regulations, is unduly burdensome and outside the purview of the Bureau's current capabilities. Human powered and unmanned vehicles, which are less secure and more susceptible to third party interference and intrusion, are prohibited for safety of the public and security of the cannabis goods.

Proposed subsections (e) through (h) clarify the measures to be taken to ensure the security of cannabis goods during transport, and are necessary to clearly identify the methods needed to safely and securely transport cannabis goods. Requiring cannabis goods to not be visible or identifiable during transport is necessary to reduce the risk of theft or robbery, which exposes the general public to harm and danger. These measures are also necessary to prevent diversion of product into the illegal and unregulated market. Securely locking the product in a box within the interior of the vehicle, and not permitting the vehicle to be left unattended in a residential neighborhood is intended to discourage theft and protect public safety.

Proposed subsection (i) is required to help deter theft and unauthorized entrance into the vehicle. In the case a vehicle containing cannabis goods is burglarized, an alarm would help alert the licensee, employees, and enforcement personnel about the intrusion, and would deter such criminal behavior.

Proposed subsection (j) is necessary to ensure that already tested product will arrive at its destination in the same quality and quantity as it was in before transport occurred, thereby limiting the risk of adulteration of cannabis goods. This requirement also ensures protection of the public health and safety and reduces the likelihood of diversion into the illegal or unregulated market.

Proposed subsections (k) and (l) specify the transport routes that can be taken and items that may be transported. Specifically, these subsections provide that transport shall be done between licensees and without unnecessary deviations. These subsections also clarify the goods that can be transported, which is necessary to ensure cannabis goods stay within the designated supply chain and prevents diversion into the illegal and unregulated market. Limiting the transport to only traveling between licensees shipping or receiving cannabis goods and its own licensed premises, ensures the licensee is not transporting mixed goods - cannabis goods and non-cannabis goods, except for cannabis accessories and licensees' branded merchandise or promotional materials. This limitation reduces unwarranted exposure to potential diversion and contamination. The proposed subsections also recognize the need for business efficiency and flexibility in transport. By allowing a distributor to transport more than one cannabis shipment at a time, this subsection reduces the number of transport trips and associated impacts on the environment and roads. Allowing a distributor to transport more than one cannabis shipment at a time also allows a distributor to increase the economies of scale.

Proposed subsection (m) allows the Bureau to inspect transport vehicles' trailers transporting cannabis goods and specifically permits access to all licensed premises. This subsection is necessary for the Bureau to carry out its enforcement duties and responsibilities under the Act to ensure statutory and regulatory compliance. This subsection also provides clarification to licensees that vehicles used to transport cannabis goods may be inspected by the Bureau at any licensed location, or during transport, to ensure the vehicle is properly equipped, carrying the required documentation, and contains a shipment compliant with the statute and regulations.

Proposed subsection (n) clarifies that when it is not operationally feasible to transport cannabis goods inside of a vehicle because the licensed premises that the cannabis goods are being transported to and the premises they are being transported from are within the same building or on the same parcel of land, then the distributor may transport the goods by foot, hand truck, fork lift, or other similar means. This section is necessary to provide clarity on the transportation requirements. The Bureau has learned that some local jurisdictions have strictly enforced the regulations and have required licensees to load a truck and drive it around the block and back to the same building for reloading. Therefore, the Bureau determined it was necessary to clarify when a distributor licensee is not required to use a vehicle for the transportation of cannabis goods.

This section will provide licensees clear direction on where they can transport and how they can transport cannabis goods. It also ensures that cannabis goods are transported safely.

§ 5312. Required Transport Vehicle Information

The purpose of this section is to clarify the additional transport vehicle requirements that are applicable only to distribution licensees. Proposed subsection (a) requires licensees to provide proof that the licensed distributor owns or holds valid lease of the vehicle and/or trailer that they plan to use for transport. This subsection is necessary because it ensures that all licensed distributors are using vehicles and trailers that they have a legal right to use.

Proposed subsections (a)(1) and (a)(2) require that the licensee provide the Bureau with information vital to the identification of the vehicle that is to be used for distribution. This is necessary because to effectively monitor and track these vehicles, the Bureau must first be able to identify the vehicles. Proposed subsection (a)(3) requires that the licensee provide the Bureau with proof of auto insurance that is in compliance with California State Law, as all vehicles on the road must carry auto insurance. This requirement ensures that licensees are abiding by all State laws and regulations, and also protects licensees in case of accident or loss of cannabis goods.

Proposed subsection (b) requires that a distributor licensee inform the Bureau of the information required in subsection (a), prior to use of a vehicle and/or trailer in the transportation of cannabis goods. This is necessary to allow the Bureau to continue to effectively monitor the activities of the licensee. It is imperative that the Bureau be informed of what vehicles a licensee is using to transport cannabis goods, to effectively monitor the distribution chain.

Proposed subsection (c) requires that a distributor licensee provide the Bureau with written notice within 30 days if any information required by the section changes. The Bureau needs to have accurate, up-to-date information regarding their licensees in order to take any necessary enforcement action, and ensure compliance with the laws and regulations. The Bureau has determined that 30 days is a fair and appropriate amount of time to require the notice, as most notifications for a change in the information provided upon licensure are required within 10 business days.

§ 5313. Transport Personnel Requirements

In the proposed regulation, the minimum age for drivers and passengers of licensed transport vehicles is 21 years old. The legal age for a person without a physician recommendation to possess cannabis goods is 21 or older. Oftentimes, a licensee with an M-designation also has an A-designation. The Bureau finds that extending A-designation age restrictions to all licensees is integral for the protection of minors. Specifically, this requirement assists in limiting a minor's access to cannabis goods. Permitting only a licensee, an employee of a licensee, or security personnel to be present during transport ensures that no unauthorized persons have access to the cannabis goods during transport. This section is necessary to ensure that cannabis goods are transported in a safe manner by persons qualified to transport cannabis goods thus ensuring the protection of the public.

§ 5314. Shipping Manifest

Business and Professions Code section 26070, subdivision (e) requires that an electronic shipping manifest, as prescribed by the licensing authority, be completed by the distributor prior to transporting cannabis or cannabis products. The section also requires that the distributor "securely transmit the manifest" to the Bureau and the licensee that will be receiving the cannabis goods.

Proposed section 5314 clarifies the process for preparing a shipping manifest and the information that must be contained in shipping manifests, as required in Business and Professions Code sections 26067 and 26070. Proposed subsection (a) specifies when a shipping manifest is required, to provide clarity to the licensee, while subsection (b) specifies who the shipping manifest must be transmitted to. Proposed subsection (c) requires licensees to utilize the shipping manifest to verify the cannabis goods being transported, and clarifies who is responsible for ensuring the accuracy of the shipping manifests and corresponding cannabis goods. This is necessary to provide accountability. Proposed subsection (d) requires that shipping manifests accompany every transport of cannabis goods, and proposed subsections (e) and (f) allows for a shipping manifest to be completed outside of the track and trace system, to account for licensees that do not yet have a track and trace system in place, and specifies who is responsible for transmitting the shipping manifest to the Bureau.

This proposed section establishes when and how a shipping manifest is to be generated, and the information that must be contained within. By clearly stating the information licensees are required to have on their shipping manifest, the proposed regulations allow for

uniformity and consistency of records across licensees and increase the speed and effectiveness of Bureau enforcement investigations, and tracking of diverted cannabis goods. Uniform manifests amongst the licensees will also allow the Bureau to better train enforcement officers on what records to expect, which will better enable them to inspect a shipment of cannabis goods. The better informed, prepared, and trained Bureau representatives and other law enforcement officers are, the better positioned they will be to identify and stop unauthorized activity, including entry of unauthorized cannabis into the market and diversion of cannabis goods.

If a shipping manifest is incomplete or does not have specific information regarding the cannabis goods being shipped or the intended destination, an enforcement officer would have a difficult time determining the legality and validity of the shipment. These proposed regulations are necessary to reduce the risk of diversion, and ensure cannabis goods stay within the regulated market through efficient tracking of cannabis goods during distribution.

§ 5315. Distributor Transport Only License

Proposed section 5315 provides for the requirements of a distributor transport only license, where such license only authorizes the transport of cannabis goods between cultivation, manufacturing, and distribution licensees, with the exception that immature plants and seeds may be transported to a retailer or to the retailer portion of a microbusiness. Proposed subsection (a) also clarifies the restrictions of distributor transport only licenses, prohibiting the transport of any cannabis goods to a retailer, unless the cannabis goods are immature plants and seeds from a licensed nursery.

Proposed subsections (b)—(d) require an application for a distributor transport only license to meet the same requirements for a general distributor license application, except for fees, which may depend upon whether the distributor transport only licensee is self-transporting or transporting for hire. These subsections also specify that the distributor transport licensee shall comply with the same requirements for a general distributor license, aside from testing and quality assurance requirements.

Proposed subsections (e)—(f) prohibit a distributor transport only licensee from the following activities: holding title to any cannabis goods, unless the licensee also holds a license for cultivation, manufacturing, retailer, or microbusiness; engaging in delivery of cannabis goods; engaging in the wholesale, destruction, packaging, labeling, or storing of cannabis goods; or arranging for the testing of cannabis goods.

Proposed subsection (g) would provide an exception to subsection (e) by allowing a distributor transport only licensee that is licensed to engage in self-distribution and whose premises will be on the same property as their cultivation or manufacturing premises to not be required to comply with the security provisions contained in proposed Article 5 of these regulations. This is necessary because the Bureau received a lot of feedback from licensees regarding the difficulty in complying with the Bureau's security requirements when their primary premises is a cultivation premises that may not have electricity or access to the internet. Further, the Bureau determined that the transportation only premises were small and primarily used for storage of records. The Bureau determined it was necessary to assist

licensees in lowering their costs by not requiring security measures in situations where they are not needed.

This section is necessary to ensure that cannabis goods are properly handled throughout the supply chain, so they can safely and securely reach the consumer without diversion, adulteration, or other contamination. A distributor transport only license allows for efficiency in the distribution of cannabis goods. These licensees that specifically only engage in transport only services, will be relieved of the obligations and requirements for testing and quality assurance. To ensure that the limitations are strictly followed, distributor transport only licensees are prohibited from certain activities, such as transporting to a retailer, unless it is specific cannabis goods not subject to testing. These restrictions are necessary to ensure that cannabis goods that have not been tested do not end up in the possession of an ultimate end consumer.

§ 5400. Access to Retailer Premises

This proposed regulation clarifies who may gain access to the licensed premises of a retailer. The purpose of this proposed regulation is to limit access to the licensed premises of a retailer to authorized individuals and to reduce or eliminate the exposure of minors to cannabis.

Business and Professions Code section 26140, subdivision (a) prohibits A-designated licensees from, selling cannabis goods to persons under 21 years of age, allowing persons under 21 years of age onto the licensed premises, or employing persons under the age of 21 years of age. Under subdivision (c) of section 26140, M- designated licensees may allow individuals who are at least 18 years of age and possess a valid physician's recommendation onto the premises. Under this proposed section, M-designated licensees may also sell cannabis goods to individuals who are at least 18 years of age and possess a valid physician's recommendation.

Consistent with Business and Professions Code section 26140, proposed subsection (a) of this proposed regulation restates the requirement that persons under the age of 21 should not be allowed onto the licensed premises of a retail licensee for clarity and convenience.

Subsection (b) of the proposed regulation restates the requirement that M-designated licensees may allow individuals who are at least 18 years of age who have a valid physician's recommendation for medicinal cannabis for clarity and convenience.

Subsection (c) of the proposed regulation provides an exception to subsection (a) for M-designated licensees. Under subsection (c) of the proposed regulation, a retailer who holds both an M-designated license and an A-designated license may allow individuals who are at least 18 years old and possess a valid physician's recommendation to access the licensed premises and is included for clarity and convenience.

This proposed regulation is necessary because it clarifies who a licensed retailer may allow to access the licensed premises as prescribed by Business and Professions Code section 26140. This clarity is important to limit access of cannabis goods by a minor or

unauthorized individual and is in furtherance of the Bureau's statutory mandate to ensure protection of the public as the highest priority.

§ 5401. [Reserved]

§ 5402. Customer Access to the Retail Area

This proposed regulation specifies who may access the retail areas of a retailer's licensed premises and provides certain requirements for retail areas accessible by customers.

Business and Professions Code section 26070, subdivision (j) requires that a licensed retailer implement security measures that are reasonably designed to prevent unauthorized entrance into areas containing cannabis goods and to prevent theft of cannabis goods from the premises. Subdivision (j)(1) of Section 26070 requires retailers to prohibit individuals from remaining on the licensee's premises if they are not engaging in activity expressly related to the operations of the retailer.

In furtherance of these statutory requirements, subsection (a) of the proposed regulation clarifies that the retailer must use to confirm the age of a customer before allowing the customer into the retail area. Under this proposed subsection, a retailer would be required to inspect and confirm the customer's identification as specified in proposed section 5402.1. A retailer may only allow a customer into the retail area after properly confirming the customer's identification, and if necessary, the customer's physician's recommendation. The purpose of this proposed subsection is to protect children and minors by assuring that only appropriately aged customers enter the retail area to purchase cannabis goods. This proposed section will also ensure that retailers are properly confirming the age of customers before allowing the customers to enter the retail area.

Subsection (b) of the proposed regulation requires that an employee of the licensee be present in the retail area any time there are customers in the retail area. The purpose of this proposed subsection is to decrease the risk of theft or diversion; unsupervised access to the retail floor area may result in the licensee losing control over the premises, which may lead to an increased risk of theft, diversion, or other unauthorized activity.

Subsection (c) of the proposed regulation requires that all sales of cannabis goods, except for sales through delivery, take place in the retail area. The purpose of this proposed subsection is to reduce the risk of theft or loss. By requiring the sale of cannabis goods to only take place in designated areas, the potential for a licensee losing control over their licensed premises is diminished. The retail area is the only area in which cannabis goods for sale may be displayed. By requiring all sales to be conducted in the controlled environment of the retail area, the risk of loss and illegal diversion is reduced.

§ 5403. Hours of Operation

This proposed regulation specifies the hours during which a retailer may sell and deliver cannabis goods. The proposed regulation prohibits a licensed retailer from selling or delivering cannabis goods between the hours of 10:00 p.m. to 6:00 a.m. The Bureau has determined that during these hours, there is a greater risk of crime or diversion because it is

dark and there are fewer people in public, factors that increase the likelihood of criminal activity. By requiring that retailers not be open to the public during these hours, the risk of criminal activity is reduced. During these hours, the retailer must be closed to the public and will be required to follow certain security requirements found in proposed section 5403.1. This requirement would minimize the potential and opportunity for an individual with the intent to rob or steal cannabis goods, to simply walk into the retailer and find product on display in the retail area, cash in the registers, and employees on the premises, at times when those on the premises may be more vulnerable and exposed. Therefore, the risk of robbery or other crime is lowered. This proposed section is also beneficial to ensuring the protection of the public as the highest priority.

§ 5403.1. Requirements While Not Open for Business

This proposed regulation specifies security requirements that a retailer must comply with during the hours the retail premises is not open for retail sales. The purpose of this proposed regulation is to reduce the risk of theft or other loss of cannabis goods while the licensed retail premises is not open for business and potentially unoccupied by the licensee's employees.

Subsection (a) of the proposed regulation specifies that while the retail premises is not open for to the public for retail sales, the retailer must securely lock the premises with commercial grade door locks. The purpose of this proposed subsection is to reduce the risk of loss due to theft as the chance of theft is minimized if the premises is securely locked.

Subsection (b) of the proposed regulation requires that the retail licensee utilize an active alarm system while the licensed premises is not open to the public for retail sales and the licensee or its employees are not on the licensed premises. The purpose of this proposed subsection is to reduce the risk of loss due to theft. The use of an alarm system will deter potential thieves and will notify the licensee of potential break-ins at the premises.

Subsection (c) of the proposed regulation requires the retailer to only allow employees and other authorized individuals to access the licensed premises when the premises is not open to the public for retail sales. It is reasonable to expect that employees and other individuals will be required to access the licensed premises even after the retailer is closed for retail sales. The purpose of this proposed subsection is to ensure that the licensee and its employees are in control of the licensed premises, thereby reducing the risk of loss due to theft. Security is very important in operating commercial cannabis business. Allowing a licensee to allow other unauthorized individuals on the licensed premises may result in the licensee losing control over who enters and accesses the premises, which may result in an increased risk of theft, diversion, or other unauthorized activity. Additionally, an unlicensed person is not subject to the rules and regulations for operating a licensed retail premises. By limiting access to only those authorized individuals who have specific business on the premises, the risk of loss due to theft is reduced. This proposed subsection also provides additional clarification as to who may be considered an authorized individual under this section, which includes persons there for legitimate business activities.

§ 5404. Retail Customers

The purpose of this proposed section is to clarify which individuals a retail licensee may sell adult-use cannabis goods to and which individuals a retail licensee may sell medicinal cannabis goods to. The proposed subsection also reiterates the requirement that a retailer must confirm the age of a customer. Business and Professions Code section 26140, subdivision (a)(4) prohibits an A-designated licensee from selling cannabis goods to any person who is not able to produce documentation indicating that they are 21 years old or older. Subdivision (c)(3) allows an M-designated licensee to sell medicinal cannabis goods to a medicinal cannabis patient or primary caregiver who can produce documentation indicating that they are at least 18 years old and possess a valid physician's recommendation for medicinal cannabis.

Subsection (a) of this proposed regulation restates the requirement found in Business and Professions Code section 26140, subdivision (a)(4) pertaining to the sale of adult-use cannabis goods. This proposed subsection also clarifies that a retailer is required to confirm the age and identity of each customer according to the requirements of proposed subsection (c) of this section. The restatement of the statutory requirement provides additional clarity on how retailers are expected to verify the age of an adult-use customer prior to selling the customer adult-use cannabis goods, and emphasizes the importance of restricting access of cannabis goods to only those individuals of age.

Subsection (b) of the proposed regulation restates the requirement found in Business and Professions Code section 26140, subdivision (c)(3) pertaining to the sale of medicinal cannabis goods. This proposed subsection also clarifies that a retailer is required to confirm the age and identity of a medicinal cannabis customer, as well as the customer's physician's recommendation as required in proposed subsection (c) of this section. The restatement of the statutory requirement provides additional clarity on how retailers are expected to verify the age and physician's recommendation of a medicinal customer prior to selling the customer cannabis goods.

Proposed subsection (c) clarifies what forms of documents of identification a customer may provide to a retailer to confirm the age of the customer. Proposed subsection (c)(1) clarifies that a document issued by a government entity that contains a minimum amount of identifying information may be used by a customer to confirm their age and identity to a retailer. The information required is not easy to change and is consistently present on many government issued identifications. The Bureau has determined that a document of identification issued by a government entity is reasonably likely to allow a retailer to effectively confirm the age and identity of the potential customer. Additionally, this type of document is reasonably difficult to falsify and the methods for verifying the authenticity of the document can easily be employed by the retailer.

Proposed subsection (c)(2) clarifies that a valid identification card issued to a member of the armed forces, containing the name, date of birth and a photo, may be used by a customer to confirm their age and identity to a retailer. The Bureau has determined that a military identification card is reasonably likely to allow a retailer to effectively confirm the

age and identity of the potential customer. Additionally, this type of document is reasonably difficult to falsify and the methods for verifying the authenticity of the document can easily be employed by the retailer.

Proposed subsection (c)(3) clarifies that valid passport issued by the United States or a foreign government may be used by a customer to confirm their age and identity to a retailer. The Bureau has determined that a valid passport is reasonably likely to allow a retailer to effectively confirm the age and identity of the potential customer. Additionally, this type of document is reasonably difficult to falsify and the methods for verifying the authenticity of the document can easily be employed by the retailer.

§ 5405. Cannabis Goods Display

This proposed section clarifies the requirements for the display of cannabis goods. The purpose of this section is to reduce the risk of loss due to theft and to reduce or eliminate the exposure of minors to cannabis. The provisions in this proposed section also aim to protect the health and wellness of cannabis customers by ensuring that cannabis goods purchased from the retail premises are free from contamination.

Proposed subsection (a) of this proposed regulation requires that any cannabis goods displayed by the retailer for inspection by customers shall only be displayed in the retail area. The purpose of this subsection is to reduce the risk of loss due to theft by limiting the use of displays. the retail area is required to be monitored by video surveillance.

Additionally, employees of the retailer are required to be physically present in the retail area while customers are there. By limiting the display of cannabis goods to the controlled environment of the retail area, a retailer will be able to reduce the risk of theft as the cannabis goods will constantly be monitored and controlled by employees and monitored by video surveillance.

Proposed subsection (b) of the proposed regulation allows a retailer to remove cannabis goods from the product packaging and place it in a separate container for display purposes. This will allow customers to inspect the cannabis goods either visually, or by touch or smell. Proposed subsection (c) also requires that any cannabis goods removed from the packaging and placed in display containers not be readily accessible to customers. The proposed subsection requires that these display containers be provided to customers for inspection by retailer employees. The employees are then required to remain with the customer while they inspect the containers of cannabis goods. The purpose of this proposed requirement is to reduce the risk of loss due to theft. By requiring retailer employees to assist customers with the display containers, the risk of customers potentially stealing the contents of the containers is greatly reduced, and provides accountability for the good. Additionally, it is beneficial in educating the customers, and helping them understand the cannabis goods they are interested in purchasing, should they have any questions or concerns regarding the product.

Proposed subsection (c) of the proposed regulation protects the health and safety of customers by preventing retailers from selling any products that are removed from their

packaging and used for display. This proposed subsection requires that any product removed from its packaging for display purposes is destroyed once it is no longer being used as display. This ensures that all product sold to customers is still sealed in packaging and free from potential adulteration. This requirement also ensures that any cannabis goods used for display will not be sold by a retailer to customers.

§ 5406. Cannabis Goods for Sale

The purpose of this proposed regulation is to protect the health and wellness of cannabis customers by requiring the retailer to ensure that any cannabis goods sold to customers have been properly tested as required by MAUCRSA and that the cannabis goods are safe for consumption.

Proposed subsection (a) requires retailers to ensure that any cannabis goods sold by the retailer have come from a licensed distributor or licensed microbusiness. The Act requires that all cannabis goods sold by a retailer first move through a licensed distributor for quality assurance and laboratory testing. This subsection places the responsibility on the retailer to ensure that any cannabis goods they sell complies with the requirements of the Act. This would also prohibit the retailer from selling cannabis goods that were not obtained through proper channels. The purpose of this subsection is to ensure that all cannabis goods sold by retailers have undergone all of the safety checks and testing required by the Act, thereby assuring that all cannabis goods intended for sale are safe for consumption.

Proposed subsection (b) requires that a retailer verify that any cannabis good sold by the retailer has not exceeded the expiration or sell-by date on the product packaging, if one is provided. The purpose of this subsection is to protect the health and wellbeing of cannabis customers by ensuring that retailers do not provide customers with cannabis goods that are potentially harmful.

Proposed subsection (c) of the proposed section requires that a retailer verify that all manufactured cannabis goods sold by the retailer complies with the specific requirements found in the Act and the regulations developed by the California Department of Public Health's Manufactured Cannabis Safety Branch. There are a number of requirements for manufactured cannabis products found in the Act and the regulations. Many of the requirements are designed to ensure that the manufactured cannabis products are safe for consumption. Although manufacturers are already responsible for ensuring that the cannabis products they manufacture comply with all of the legal requirements, this proposed regulation would also place the responsibility on retailers. As the final licensee to handle the manufactured cannabis products before the cannabis goods are sold to a customer, it is important that the retailer ensure that the manufactured cannabis products comply with all of the legal requirements before making the products available to customers for consumption.

Subsection (d) of the proposed section requires the retailer to verify that all cannabis goods sold by the retailer have undergone the laboratory testing required by the Act. Although

distributors and testing laboratories are already responsible for ensuring that cannabis goods transported to a retailer have been properly tested, this proposed regulation would also place the responsibility on retailers. As the final licensee to handle the cannabis goods before the cannabis goods are sold to a customer who will consume the cannabis goods, it is important that the retailer ensure that the cannabis goods have been properly tested and are thus safe for customers to consume.

Subsection (e) of the proposed section requires the retailer to verify that any cannabis goods sold by the retailer are properly packaged and labeled as required by the Act and the regulations released by all three of the licensing authorities. The packaging of cannabis is important because the Act requires specific packaging requirements with the intention of preventing young children from accessing the cannabis goods. Similarly, the labeling of cannabis goods is important because customers obtain information about products from their labeling. There are specific requirements within the Act and the regulations from the licensing authorities that require specific information to be included on the product's label. Although distributors, cultivators, and manufacturers are already responsible for ensuring that cannabis goods transported to a retailer are properly packaged and labeled, this proposed regulation would also place the responsibility of final review of packaging and labeling on retailers. As the final licensee to handle the cannabis goods before the cannabis goods are sold to a customer who will consume the cannabis goods, it is important that the retailer ensure that the cannabis goods have been properly packaged and labeled so that young children do not access the cannabis goods and the customers purchasing the cannabis goods have access to the information that is required to be placed on the product labels.

Subsection (f) of the proposed section requires the retailer to verify that all cannabis goods comply with all other requirements found within the Act and the applicable regulations. This subsection makes the retailer responsible for verifying that any cannabis goods sold by the retailer comply with all other legal requirements not specifically stated in this section. As the final licensee to handle the cannabis goods before the cannabis goods are sold to a customer who will consume the cannabis goods, it is important that the retailer ensure that the cannabis goods comply with all of the legal requirements, which are geared towards ensuring the public's health and safety, before making the cannabis goods available to customers. Every licensee in the supply chain has a responsibility to ensure the safety of the product they are moving forward, as they receive the gains and benefits from selling the product down the supply chain. As the licensee with control over the cannabis goods before it is sold to the customer, the retailer is the last licensee with the opportunity to prevent unauthorized access to cannabis goods, or access to harmful cannabis goods.

§ 5407 Sale of Non-Cannabis Goods on Premises

This proposed section clarifies that a retailer may only sell specific products, limited to cannabis goods, cannabis accessories, and any licensees' branded merchandise or promotional materials. This is to ensure there is no cross-contamination from non-cannabis related goods, and to preserve the integrity of the goods sold. The privileges of licensure

only allow for commercial cannabis activities, it does not include other commercial enterprises, which this proposed section is necessary to clarify and make specific. The Bureau has determined that branded merchandise and promotional materials are closely related to commercial cannabis activity and therefore, can be sold. This provision also provides consistency between what distributors can transport and what retailers can sell.

§ 5408. Sale of Live Plants and Seeds

This proposed section provides the requirements for the sale of live cannabis plants and seeds by retailers. The proposed section also protects the health and wellness of customers by prohibiting retailers from selling products that may be harmful.

Subsection (a) of the proposed regulation clarifies that a retailer may engage in the sale of live immature cannabis plants and cannabis seeds so long as the requirements in the proposed section are met.

Subsection (a)(1) of the proposed section requires that any cannabis plants sold by a retailer are not flowering. The purpose of this subsection is to protect the health and wellness of customers who purchase cannabis plants from a retailer. A cannabis plant that is flowering contains cannabis flowers that the purchaser of the plant may be able to consume. Any cannabis found on a live cannabis plant is unlikely to have been tested and may not be safe for consumption by a customer. Therefore, retailers may not sell live pants that already contain cannabis flowers.

Subsection (a)(2) of the proposed section requires that any cannabis plants or seeds sold by a retailer must have originated from a licensed nursery or a microbusiness authorized to engage in cultivation. The Act requires that all cannabis goods sold by a retailer be obtained from other licensees. Retailers are prohibited from selling cannabis goods that have not gone through the proper supply chain. The purpose of this proposed subsection is to ensure that retailers only sell cannabis plants and cannabis seeds that were obtained through the proper supply chain as required by the Act.

Subsection (a)(3) of the proposed section requires that all cannabis plants and cannabis seeds sold by a retailer must be affixed with a label indicating that the plant or seeds have not been tested as required by the Act. Business and Professions Code section 26110, subdivision (a) exempts immature cannabis plants and cannabis seeds from the testing requirements of the Act. The purpose of this proposed subsection is to eliminate any confusion that may arise in the purchase of a cannabis plants or cannabis seeds from a retailer. This proposed subsection ensures that customers who purchase cannabis plants or cannabis are fully aware that the products have not undergone the same laboratory testing procedures that are required for other cannabis goods for sale.

Subsection (b) of the proposed section prohibits retailers from selling other types of live plants outside of cannabis plants. The purpose of this section is to eliminate any confusion that may result if retailers carried other types of plants in addition to cannabis plants. Customers, Bureau staff, and law enforcement may be confused as to which plants are cannabis plants and what plants are not if a retailer sold a variety of different kinds of

plants. In order to reduce the risk of this confusion, retailers will be limited to only selling cannabis plants under this proposed subsection.

Subsection (c) of the proposed section prohibits a retailer from applying or using pesticides on a cannabis plant for sale. The proposed subsection also prohibits a retailer from causing pesticides to be applied or used on cannabis plants for sale. The purpose of this proposed subsection is to protect the health and well-being of retailer employees and customers who purchase cannabis plants from retailers. Since the Act does not require cannabis plants for sale to be tested, if pesticides were applied to cannabis plants for sale, there would be no reliable method for identifying whether the cannabis produced from the plant would be unsafe to consume due to the pesticide use. Therefore, in order to ensure that cannabis sold by retailers do not contain harmful levels of pesticides, the use of pesticides is completely prohibited on these plants.

§ 5409. Daily Limits

This proposed section provides the maximum amount of cannabis goods that a retailer may sell to an individual customer. The amounts found in this section mirror the legal possession limits for adult-use cannabis users found in Health and Safety Code section 11362.1 and the legal possession limits for medicinal cannabis patients found in Health and Safety Code section 11362.77. The purpose of this proposed section is to prevent retailers from selling an amount of cannabis goods to a customer which would result in the customer being in violation of the legal possession limits for cannabis. Additionally, placing a limit on the amount an individual can purchase reduces the risk of the customer becoming a target of criminal activity as they leave the retail premises with a large amount of cannabis goods. Also, limiting the amount that can be purchased in a single day reduces the risk of a customer illegally reselling cannabis goods purchased from a retailer.

The proposed regulation prohibits a retailer from selling a customer an amount of cannabis goods in excess of the amounts stated in the proposed section to a single customer in a single day. The Bureau has determined that requiring retailers to track the amount of cannabis sold to a single customer in a single day is the most effective method of balancing the Bureau's interest in reducing the risks stated above, while limiting the amount of resources that a retailer would have to invest in developing a system for tracking the amounts purchased by customers. The proposed subsection does not require retailers to track the total amount of cannabis goods possessed by a customer. A retailer is only required to track the amount of cannabis goods sold to the customer by that retailer.

Subsection (a) of this proposed section provides the amount of adult-use cannabis goods that a retailer may sell to a single customer in a single day. Under the proposed subsection, a retailer may sell up to 28.5 grams of non-concentrated cannabis, eight grams of concentrated cannabis as defined in the Act, and six immature cannabis plants. The limits found in this proposed section are identical to the possession limits for adult-use cannabis found in Health and Safety Code section 11362.1. The purpose of this subsection is to clarify the specific amount of adult-use cannabis goods in each category that a retailer may sell to a single customer in a single day.

Subsection (b) of this proposed section provides the amount of medicinal cannabis goods that a retailer may sell to a single patient or primary caregiver in a single day. Under the proposed subsection, a retailer may sell up to eight ounces of medicinal cannabis in the form of dried mature flower or the plant conversion or 12 immature cannabis plants. The limits found in this proposed section are identical to the possession limits for adult-use cannabis found in Health and Safety Code section 11362.77. The purpose of this subsection is to clarify the specific amount of medicinal cannabis goods that a retailer may sell to a single customer in a single day.

Subsection (c) of the proposed section provides an exception to subsection (b). Under section 11362.77, subsection (b) of the Health and Safety Code, a medicinal cannabis patient or primary caregiver may legally possess an amount of medicinal cannabis in excess of the limits stated in statute if the physician's recommendation indicates that the statutory possession limits does not meet the patient's medicinal needs. In this case, a patient may legally possess an amount of cannabis that is consistent with the patient's needs. This proposed subsection clarifies that a retailer may sell a medicinal cannabis patient an amount of medicinal cannabis goods that meets the patient's needs so long as the patient's physician's recommendation indicates this. The purpose of this proposed subsection is to allow retailers to sell medicinal cannabis goods to patients in amounts that are consistent with the requirements of Health and Safety Code section 11362.77.

Proposed subsection (d) clarifies that the medicinal and adult-use limits contained in this section cannot be combined to allow a customer to purchase an amount of cannabis goods that exceeds either of the limits set in this section. This proposed subsection is necessary to eliminate any confusion regarding the purchase limits in this section and to address the issue of whether a medicinal patient may purchase the maximum amount allotted for medicinal cannabis goods in addition to the maximum amount allotted for adult-use cannabis goods. The proposed subsection clarifies that a medicinal patient may not.

§ 5410. Customer Return of Cannabis Goods

This proposed section provides an overview on how a retailer must handle customer returns of cannabis goods. The proposed section also states what a retailer must do with cannabis goods that are returned by a customer. The purpose of this section is to protect the health and safety of customers by reducing the risk of customers being sold adulterated cannabis goods. All cannabis goods sold by a licensed retailer are required to be tested by a licensed testing laboratory prior to sale. If the cannabis goods are then returned to the retailer, there is no reasonable method for effectively ensuring that the cannabis goods were not contaminated or adulterated in any way, after being sold, and prior to return.

Proposed subsection (a) of the proposed section provides a definition for the term "customer return" as the term is used in this proposed subsection. This is important in order to differentiate the types of transactions covered in this proposed regulation from other types of returns such as returns between licensees. For clarity, this section is limited to discussing the return of cannabis goods from customers to retailers.

Proposed subsection (b) of the proposed section clarifies that a retailer may accept returns of cannabis goods from customers. This section does not require dispensaries to accept returns, but gives them the ability to accept them if they wish.

Proposed subsection (c) prohibits a retailer from reselling cannabis goods that have been returned by a customer. Since there is no way for a retailer to be certain that the returned cannabis goods are not defective or have not been adulterated in any way, the retailer cannot resell the returned cannabis goods to another customer. The purpose of this proposed subsection is to protect the health and wellness of customers by reducing the risk of customers obtaining cannabis goods that may have been adulterated.

Proposed subsection (d) requires that any cannabis goods abandoned on the retailer premises be treated as a return and not be allowed to be resold. Since there is no way for a retailer to be certain that the abandoned cannabis goods are not defective or have not been adulterated in any way, the retailer cannot sell the abandoned cannabis goods to customer. The purpose of this proposed subsection is to protect the health and wellness of customers by reducing the risk of customers obtaining cannabis goods that may have been adulterated.

Proposed subsection (e) requires that a retailer destroy all returned cannabis goods in accordance with proposed section 5054 and 5055 of this division. This requirement further ensures that cannabis goods that have been returned will not be resold to other customers, or diverted. The purpose of this proposed subsection is to protect the health and wellness of customers by reducing the risk of customers obtaining cannabis goods that may have been adulterated.

§ 5411. Free Cannabis Goods

This proposed regulation provides the requirements a retailer must adhere to in order to provide free cannabis goods or free cannabis accessories. The purpose of this proposed regulation is to ensure that licenses comply with statutory requirements, while protecting the health and wellbeing of the public.

Business and Professions Code section 26153 prohibits a licensee from giving away cannabis goods or cannabis accessories as part of a business promotion or other commercial activity. Subsection (a) of the proposed regulation clarifies that a retailer generally may not provide free cannabis good to any person. The proposed subsection (a) also clarifies that a retailer would not be able to allow another person that is not employed by the retailer to provide free cannabis goods to any person on the licensed premises.

Retailers providing free samples of cannabis goods to customers was a practice engaged in by many retailers prior to the enactment of the Act. It is necessary to clarify that under the act, the practice of providing free samples to customers is no longer permitted.

Proposed subsection (b) of the proposed regulation provides an exception to proposed subsection (a). Proposed subsection (b) allows a retailer to provide medicinal cannabis goods to medicinal cannabis patients if certain requirements are met. The ability to provide free medicinal cannabis goods to certain patients is limited to M-retailers, M-non-storefront retailers, and M-microbusiness licensees who are authorized for medicinal retail sales. The

reason only these licenses may provide free cannabis goods is because the cannabis goods held by retailers are required to undergo assurance and laboratory testing. By limiting the provision of free cannabis goods to these licensees, the Bureau can ensure that all cannabis goods provided to patients under this section are safe for consumption. Additionally, providing free goods to patients does not constitute free goods as part of a business promotion, which is prohibited.

Proposed subsection (b)(1) requires retailers to only provide free cannabis goods to medicinal cannabis patients who possess an identification card. This requirement is consistent with the requirement to be exempted from sales tax as a medicinal cannabis patient. The purpose of this proposed subsection is to provide access to medicinal cannabis for those that may have difficulty in obtaining it. The Bureau has received many public comments on compassionate care use of medicinal cannabis, and the dangers and risks of restricting access to medicinal cannabis.

Subsection (b)(2) of the proposed section requires that any cannabis goods provided to a medicinal cannabis patient or primary caregiver under this section comply with all of the required laboratory testing. The purpose of this proposed subsection is to protect the health and wellbeing of medicinal cannabis consumers by prohibiting retailers from providing cannabis goods that have not been properly tested.

Subsection (b)(3) of the proposed section requires that all cannabis goods provided to a medicinal cannabis patient or primary caregiver for free under this section be properly entered into the State track and trace program as belonging to the retailer's inventory. The purpose of this proposed subsection is to allow for the accurate tracking of the movement of cannabis goods through the track and trace system as required by the Act.

Subsection (b)(4) of the proposed subsection requires that any cannabis provided to a medicinal cannabis patient or primary caregiver under this section comply with packaging requirements for leaving a licensed premises. As noted above, retailers are the final licensee to handle the cannabis goods before the cannabis goods are provided to a medicinal customer who will consume the cannabis goods. Thus, it is important that the retailer ensure that the cannabis goods have been placed in a proper package so young children do not access the cannabis goods and the package is opaque as required by statute.

Subsection (b)(5) of this proposed section requires a retailer to apply any amount provided to a medicinal cannabis patient or primary caregiver under this section to the total amount of cannabis goods that a medicinal cannabis patient or primary caregiver may purchase under proposed section 5409. The purpose of this proposed subsection is to ensure consistency between the requirements for cannabis purchased form a retailer and cannabis received by a medicinal cannabis patient or primary caregiver from a retailer under this proposed section. The reasons for limiting the amount of cannabis goods a single medicinal cannabis patient or primary caregiver may purchase would also apply to amounts of cannabis goods provided to a medicinal cannabis patient or primary caregiver under this section.

Subsection (b)(6) of the proposed subsection requires a retailer to properly record the transaction of providing free cannabis goods to a medicinal cannabis patient or primary caregiver in the state track and trace system. The purpose of this proposed subsection is to allow for the accurate tracking of the movement of cannabis goods through the track and trace system as required by the Act.

Subsection (c) of the proposed regulation clarifies that, in addition to providing free medicinal cannabis goods directly to medicinal cannabis patients and primary caregivers, a retailer may donate cannabis goods or the use of equipment to a compassionate use, equality, or similar program administered by a local jurisdiction. The subsection also requires donated cannabis goods to meet testing requirements and recorded in track and trace. The purpose of this subsection is to clarify a licensed retailer's ability to engage in philanthropic activities for locally-recognized compassionate use, equality, or other similar programs, while ensuring safe cannabis is donated and the goods are tracked properly.

§ 5412. Prohibition on Packaging and Labeling by a Retailer

This proposed section prohibits a retailer from packaging and labeling cannabis goods.

Under the Act, all cannabis goods must be tested by a licensed testing laboratory and must receive a certificate of analysis from a licensed testing laboratory before being transported to a retailer for sale to customers. To ensure that the test results are accurate, the packaging of the cannabis goods must not be opened between the time the testing occurs and the time the cannabis goods are sold to the final user. Packaging or repackaging at the retail facility may result in contamination or adulteration of the cannabis goods, which may render the test results inaccurate. In order to ensure that the laboratory testing results accurately apply to the product the customer is purchasing from a retailer, a retailer may not open the packaging or repackage cannabis goods prior to selling the cannabis goods to a customer. The purpose of this proposed section is to protect the public by ensuring accurate test results and safe products.

Subsection (a) of the proposed regulation clarifies that a retailer may not accept, possess, or sell cannabis goods that are not packaged as they will be sold at final sale. This proposed subsection will ensure that retailers do not receive any items that are not already packaged. Thus, reducing the risk that the retailer will have to package the cannabis goods themselves or sell cannabis goods that are not properly packaged and labeled.

Subsection (b) of the proposed regulation specifies that a retailer may not package or label cannabis goods. The purpose of this proposed subsection is to ensure that there is no confusion as to whether or not a retailer may engage in the packaging and labeling of cannabis goods.

Subsection (c) of the proposed regulation clarifies that a retail licensee who also holds a distribution, manufacturing, or cultivation license, may engage in packaging and labeling under the distribution, manufacturing, or cultivation license at the premises associated with the license. The purpose of this proposed subsection is to clarify any confusion regarding

whether or not a retail licensee who also holds other types of commercial cannabis licenses is still prohibited from packaging cannabis goods.

§ 5413. Exit Packaging

Business and Professions Code Section 26070.1 provides that all cannabis goods purchased by a customer shall not leave a licensed premises unless the cannabis goods are placed in a resealable child-resistant opaque package. This proposed regulation is a restatement of statutory requirements. The reason for the restatement is for the purpose of clarity.

§ 5414. Non-Storefront Retailer

This proposed regulation provides the requirements for the retail non-storefront license. The license is not included in the Act. The license is essentially a limited version of the retail license. A licensee who holds this license may engage in the retail sale of cannabis, but only through delivery. This provision reconsidered feedback received by the Bureau and allows for a lower cost option than a storefront retailer to participate in the regulated market. The purpose of this proposed regulation is to provide clarity on the requirements for obtaining and holding such a license.

Proposed subsection (a) of the proposed section provides a basic description of the license. This proposed section indicates that a licensee may engage in retail sales exclusively through delivery. The purpose of this proposed subsection is to provide a basic idea of the general activities a licensee may conduct.

Proposed subsection (b) of the proposed regulation provides the requirements for applying for a license. This proposed subsection requires that an applicant for a non-storefront retailer license submit all the information required for a retailer application. Since the non-storefront retailer license is very similar to the retailer license, the Bureau has determined that the application for a license requires the same information that would be required in non-storefront retailer license application.

Proposed subsection (c) of this proposed regulation provides the requirements for operating under a license. This proposed subsection requires licensees to comply with all requirements for licensees, with the exception of any provisions relating to public access to the licensed premises, licensing fees, and certain premises requirements. Since the non-storefront retailer license is similar to the retailer license, the Bureau has determined that it is appropriate to require licensees to comply with most of the requirements for a non-storefront retailer license except those provided in this proposed subsection. The Bureau has determined that the identified exceptions are necessary because they address particular issues that are related to the nature of licensing activities and operations.

Proposed subsection (d) of the proposed regulation specifies that the licensed premises of a non-storefront retailer licensee shall be closed to the public. Since a licensee is not authorized to engage in onsite sales of cannabis goods, there is no reason for member of the public to access the licensed premises. Therefore, to reduce the risk of theft or other loss, a licensee would be required by this proposed subsection to prohibit the public from

accessing the licensed premises. This proposed section is beneficial in allowing flexibility in license types, and allows for licensed commercial cannabis activity that helps to bring the illegal market into the regulated industry.

§ 5415. Delivery Employees

This proposed regulation provides the requirements for retailer delivery employees. Business and Professions Code section 26070, subdivision (c) requires that the driver of a vehicle transporting or transferring cannabis goods be directly employed by a licensee authorized to transport or transfer cannabis goods. The Act defines delivery as the commercial transfer of cannabis or cannabis products to a customer. Therefore, under the statute, a delivery employee of a retailer must be directly employed by that retailer. Subsection (a) of the proposed section restates the requirement regarding direct employment. The reason for the restatement is for clarity. Rather than require a licensee to refer to both the regulations and the statute for delivery employee requirements, a licensee may find the delivery employee requirements in the regulations.

Under current California law, an individual must be at least 21 years old to legally possess cannabis without a valid physician's recommendation. The Act mandates the Bureau to craft regulations that ensure a safe and secure operation of the commercial cannabis market. The Act also permits delivery by retailers; however, it does not clarify safety and security measures to be implemented. Under current California law, individuals under the age of 21 years are permitted to work and potentially deliver medicinal cannabis goods. Proposed subsection (b) requires that all delivery employees be at least 21 years old. This is a restatement of the requirement found in proposed section 5031. The purpose for restating this requirement here is for clarity. The requirements for delivery employees can be found in this chapter rather than requiring a licensee to refer to multiple chapters within the division to find the requirements for delivery employees. The purpose of this requirement is to reduce the risk of exposure of minors to cannabis.

Proposed subsection (c) requires in person deliveries. The reasoning for this requirement is so that the delivery employee can confirm the identity of the customer requesting the delivery before providing cannabis goods to the customer. This also prevents a delivery employee from leaving a delivery unattended. Additionally, the use of drones or other automated delivery vehicles would be prohibited under this subsection; such delivery methods may result in an increased risk of loss due to theft and other crimes as they may be a target for theft.

Proposed subsection (d) clarifies when a delivery begins and ends. This proposed subsection specifies that the process of delivery begins when the delivery employee leaves the licensed premises with the cannabis products to be delivered, and ends when the delivery employee returns to the licensed premises after completing the deliveries. This is important to specify when a delivery begins and ends so that delivery employees will be informed as to when they are required to comply with all of the requirements for actively performing a delivery. This proposed subsection also assures that deliveries are made in an efficient manner, with limited stops by delivery employees. If delivery drivers were to

engage in additional activities or stops while carrying large amounts or cash or product, their vehicles may render them a target for theft or other criminal activity. This proposed subsection would limit the potential for any loss or diversion if a delivery driver leaves their vehicle unattended.

Proposed subsection (e) requires that the delivery employee always carry a copy of the retailer's license, the employee's identification card, and an employee badge while making deliveries. The requirement to maintain these documents while making deliveries is required by Business and Professions Code section 19340. The requirement is restated in this proposed regulation for clarity purposes. This subsection also assures that if stopped by law enforcement or Bureau staff for inspection, drivers and the licensee's status can be properly identified.

Proposed subsection (f) requires delivery employees to confirm the age and identity of a delivery customer prior to providing the cannabis goods to the customer as required by proposed Section 5402.1 of this division. It is important for a delivery employee to confirm the age and identity of a delivery customer to ensure that the delivery customer is legally authorized to purchase and possess cannabis goods. The purpose of this proposed subsection is to ensure that cannabis goods are not delivered to minors who cannot legally purchase and possesses cannabis goods. The subsection also requires the delivery employee to place the cannabis goods into a resealable, child-resistant opaque exit package. This is necessary to comply with the requirement that cannabis goods be placed in an exit package prior to being given to a customer.

Proposed subsection (g) requires that the retailer maintain a list of their delivery employees. It is important for the retailer to maintain a list of delivery employees so that the retailer, law enforcement, and the Bureau can easily identify those individuals who are conducting deliveries for on behalf of the licensed retailer. A retailer licensee must be able to identify all of the individuals who are actively performing deliveries on behalf of the licensed retail location. Requiring identifying information of delivery drivers be kept and maintained provides the Bureau with the necessary information to properly and effectively audit the retailer. Ensuring only employees of the licensee are permitted to deliver cannabis goods and that the delivery be done in person provides the Bureau the ability to take appropriate action against a licensee's license for improper activity or malfeasance during delivery. These proposed requirements are also necessary to ensure that the delivery process is rendered as safe as possible, for the benefit of the employee, the licensee, and the public.

§ 5416. Delivery to Physical Address

Delivery is permitted under the Act, but the law does not provide any specific guidance or limitation on how to avoid conflicts with federal law or regulation. Clarity is needed to identify permissible delivery locations and methods. The Bureau's selection of acceptable delivery locations and roadways provide licensees clarity on where they can deliver. For instance, the subsection limits delivery routes to be entirely encompassed within the state; this mitigates the intersection of the State's regulation and potential conflict with federal

law. If the Bureau did not specify or identify locations where delivery could occur, licensees may interpret the silence to allow delivery at any location, including parks, near schools, and other unauthorized locations. Also, without a clear and specific recorded delivery location, Bureau enforcement and compliance investigations would be significantly impeded.

Proposed subsection (a) requires that all deliveries be made to a physical address in California. Requiring the delivery of cannabis goods to a specific physical address in California ensures that the Bureau is able to effectively track that all cannabis goods are reaching customers in California. This subsection also ensures that cannabis goods that are being delivered by licensees are not being diverted into the illegal or unregulated market or to other states.

Proposed subsection (b) requires that a delivery employee not leave the State of California while delivering cannabis goods. Requiring the delivery of cannabis goods to locations and routes wholly within the State of California helps to rectify potential conflicts with federal narcotics laws, and complies with the Act that restricts cannabis activity to within the state.

Proposed subsection (c) prevents a retailer from making a delivery to an address on publicly owned or leased land or buildings. This provision also helps to rectify potential conflicts with federal law by prohibiting deliveries to national parks, federally owned buildings, or other government-owned properties.

Proposed subsection (d) clarifies that a delivery employee may deliver to any jurisdiction within the State of California. This proposed subsection specifies where a delivery employee may deliver within the State of California, which is to any jurisdiction within the State of California. Business and Professions Code section 26090 subdivision (e) prohibits a local jurisdiction from preventing delivery of cannabis goods on public roads by a licensee acting in compliance with law. This is necessary to clarify that MAUCRSA and its implementing regulations do not impose restrictions or limit where a delivery employee may deliver, as long as it is within the State of California.

§ 5417. Delivery Vehicle Requirements

The Act mandates the Bureau to craft regulations that ensure the safe and secure operation of the commercial cannabis market. The Act permits retailers to deliver medicinal cannabis goods but does not provide clarification on how the delivery is to be executed.

The purpose of this proposed section is to mitigate potential theft, diversion into the illegal and unregulated market, and unsafe licensed activities while cannabis goods are being delivered. The provisions in this proposed section are intended to enhance public health and safety by reducing the risk of theft of product.

Proposed subsection (a) describes the requirements for a vehicle used in the delivery of medicinal cannabis goods. The vehicle is required to be an enclosed motor vehicle in order to increase public health and safety by limiting the potential for theft or other crimes while a delivery driver engages in the delivery process. This proposed subsection also requires that the vehicle be operated by a delivery employee of the retailer. This requirement is

intended to ensure that the retailer's delivery employee is in control of the movement of the cannabis goods throughout the delivery process.

Proposed subsection (b) requires that the delivery employee ensure that any cannabis goods that are being delivered are not visible to the public. This requirement serves to enhance public health and safety by limiting the risk of the delivery employee becoming a target of theft or other criminal activity.

Proposed subsection (c) provides that cannabis goods may not be left in the vehicle unattended unless the vehicle is equipped with a vehicle alarm system. This proposed subsection reduces the risk of cannabis goods being stolen from within the delivery vehicle while the delivery staff has left the vehicle to make a delivery.

Proposed subsection (d) requires that all delivery vehicles be outfitted with a device for tracking the vehicle's geographic location. The purpose of this proposed subsection is to allow the Bureau to effectively monitor delivery vehicles. 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 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 purposes. The devices 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. This is likely to happen if the device is also being used as a cellular phone. In addition, if a delivery vehicle with cannabis goods is stolen, it would be beneficial to have the GPS device inside of the vehicle for tracking purposes.

Proposed subsection (e) requires the licensee to provide the Bureau with information pertaining to delivery vehicles, including the make, model, color, VIN, license plate number, and DMV registration information. These requirements are important to assure that licensees are maintaining accurate records. They also enable the Bureau to effectively monitor whether licensees are conducting deliveries consistent with the Act and its implementing regulations.

Proposed subsection (f) allows the Bureau to inspect any vehicle that is used for delivery. This is important for the Bureau's ability to effectively monitor licensees and ensure that the delivery vehicles meet the requirements.

§ 5418. Cannabis Goods Carried During Delivery

The Act mandates the Bureau craft regulations that ensure the safe and secure operation of the commercial cannabis market. The Act does not provide clarity as to how retailers are required to accept or process orders of cannabis goods for delivery. The Act also does not specify how much product a delivery driver may carry while making deliveries.

This proposed section is necessary to enhance public health and safety by mitigating not only the loss of cannabis goods, but the potential for theft and other crimes during delivery. The proposed section also ensures that all cannabis goods leaving the retail premises with a

delivery employee are properly accounted for. 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. It also reduces the risk of a delivery driver's consumption during delivery.

Proposed subsection (a) provides that a delivery employee may not carry cannabis goods in excess of \$10,000 at any time. The purpose of this proposed rule is to limit the amount of cannabis goods that a delivery employee carries, thereby limiting the amount of cannabis goods that may be lost or diverted in the case of theft or another crime. The Bureau has determined that \$10,000 of cannabis goods is an appropriate amount because it enables a delivery driver to accept additional orders while already on the road, resulting in economies of scale. This amount also ensures that drivers do not have to drive back and forth between delivery locations, and the retail premises; reducing the amount of vehicle miles traveled will minimize potential environmental impacts associated with greenhouse gas.

Proposed subsection (b) provides that a delivery employee may only carry cannabis goods in the delivery vehicle, and may only perform deliveries for one licensed retailer at a time. The purpose of this subsection is to assure that licensees and the Bureau may effectively track the activities of that particular licensee at a given time. Permitting drivers to operate for multiple licensees or conduct other business may conflate records, comingle product, and may increase the potential for loss or diversion due to theft or other criminal activities. This subsection assures that both licensees and the Bureau may effectively track a particular licensee's activities at a given time.

Proposed subsection (c) provides that a delivery employee shall not leave the licensed premises without at least one delivery order that has been received and processed by the retailer. This subsection assures that delivery drivers are not aimlessly driving around, waiting for orders. Allowing delivery drivers to do so would not only result in potential environmental impacts associated with greenhouse gasses, but increase potential opportunities for theft or other crimes, as the driver may be a potential target.

Proposed subsection (d) provides that a delivery driver must have a delivery inventory ledger of all cannabis goods provided to the delivery driver. After each delivery, the driver must update the ledger to reflect the current inventory in its possession. This requirement serves to aid both licensees and the Bureau to effectively track product that is being conveyed by delivery drivers. Detailed record keeping helps minimize potential losses or diversion because all product would need to be accounted for. Any discrepancies in records and product could possibly be identified based on the ledger. Moreover, it provides both licensees and the Bureau additional opportunities to audit licensee and employee activities.

Proposed subsection (e) requires delivery drivers to maintain a log of all stops from the time of the driver leaves the licensed premises to the time they return to the licensed premises. This requirement, as with the ledger, serves to aid both licensees and the Bureau to effectively track the activities of the delivery employees. As with the delivery ledger, it provides both licensees and the Bureau additional opportunities to audit licensee and employee activities.

Proposed subsection (f) requires that prior to arrival at any delivery location, the licensed retailer must have received the delivery request from the customer and provided the delivery request receipt to the delivery driver electronically or in hard copy. This requirement aids the licensees and the Bureau to effectively track the activities of the delivery employees and reduces the risk of unauthorized diversion.

Proposed subsection (g) provides a list of documents a delivery driver must provide to the Bureau or any law enforcement officer upon request. Specifically, drivers must provide their inventory ledgers, delivery request receipts, and log of all stops for inspection. This enables the Bureau and law enforcement to effectively audit licensee and employee activities. It also ensures that the Bureau and law enforcement have all the information necessary to evaluate whether the delivery driver is operating in conformance with the Act and its implementing regulations.

Proposed subsection (h) provides that if a delivery driver does not have any delivery requests for a 30-minute period, they must cease making any deliveries and return to the licensed premises. This subsection serves to prevent delivery drivers from driving around aimlessly or idling while they wait for additional orders to come through, thus limiting the potential environmental impacts associated with greenhouse gasses and potential opportunities for theft or other crimes.

Proposed subsection (i) provides that upon returning to the licensed premises, all undelivered cannabis goods shall be returned to inventory and all necessary inventory and track-and-trace records be updated as appropriate. This requirement assures that the movement of cannabis goods is properly accounted for through track-and-trace and limits the potential for diversion. It also assures that retailer licensees maintain up-to-date record keeping as orders are sent and received throughout the day.

§ 5419. Cannabis Consumption During Delivery

The Act mandates the Bureau craft regulations that ensure a safe and secure operation of the commercial cannabis market. This proposed section prohibits delivery employees from consuming cannabis while making deliveries. This proposed section is necessary to protect public safety by ensuring that drivers are not operating motor vehicles and making deliveries while impaired.

§ 5420. Delivery Request Receipt

Business and Professions Code section 26090, subdivision (c), mandates that each delivery of cannabis goods be accompanied by delivery request documentation; however, the act fails to specifically identify what information is to be captured on the delivery request documentation. The Business and Professions Code also does not clearly state the manner and method of receipt collection and retention.

Proposed subsection (a) lists the information that is required to appear on the delivery request receipt. The name and address of the retailer is necessary to identify the retailer that completed the delivery. The name of the delivery employee is also important to identify the

identity of the individual employee who performed the delivery. The name of the employee who prepared the delivery is important because if the employee who delivered the medicinal cannabis goods was not the same employee who prepared the delivery, any problem with the preparation of the order would be attributable to the preparer and not the delivery employee. This information is required to identify the preparing employee. The identity of the customer who requested the delivery is important because the Bureau may need to verify the identity of the customer. The date and time the delivery request was made and completed is important for the identification of the transaction. The delivery address is necessary because the Bureau may need to verify that the delivery was made to a valid California address. Additionally, the Bureau or law enforcement may need to get in contact with the customer who requested the delivery in the event of an investigation. A description of the cannabis goods delivered, and the total amount paid for the delivery is important to identify the transaction. Additionally, information regarding the cannabis goods sold and the amount paid may be vital in the case of an investigation and to track the product was legally sold to a customer. The signature of the customer who received the delivery is important in verifying that the customer did in fact receive the order.

Proposed subsection (b) requires that the delivery employee provide the customer with a copy of the receipt and bring a copy of the receipt back to the retailer. This is important because it provides the customer with an opportunity to verify the transaction before signing the receipt. Also, requiring the maintenance of copies of all transactions allows for the Bureau to inspect all necessary records during the course of an investigation; a retailer will be able to provide information on every delivery it performed.

Proposed subsections (c) and (d) provide additional clarity by defining the terms “employee number” and “customer number” as used in this section. This is necessary to ensure that licensees understand their responsibilities to identify employees and customers under this proposed section, while protecting identification of these persons by other people which could compromise privacy and safety.

This section is necessary to comply with the requirements of the Act and to effectively track deliveries of cannabis goods. Ensuring that every transaction is associated with a legitimate sale to a customer is vital to preventing the entry of untested cannabis goods into the market and diversion of cannabis goods into the illegal unregulated market. By clearly identifying what information is required, this section provides the Bureau unique and specific information which can be utilized during retailer audits. Requiring the receipt be prepared in advance of the delivery helps to prevent diversion of medicinal cannabis goods and ensures that all medicinal cannabis goods leaving the retailer are properly accounted for.

§ 5421. Delivery Route

If a specific delivery route is not defined, the delivery employee has unfettered freedom of movement. This freedom could potentially increase the opacity of the activity, making diversion and illegal activity more likely to occur. Without a clearly defined delivery plan, enforcement of proper and improper activity is more difficult.

This section is necessary to ensure cannabis goods stay within the designed supply chain and prevent diversion and other illegal activity. This section requires that delivery employees travel between the licensed retailer to the delivery address, from one delivery address to another delivery address, or from a delivery address back to the licensed retail premises. This requirement reduces the duration that product is en route, which lowers the risk of loss due to theft or other crime. This section also recognizes the need for flexibility in delivery of cannabis goods and provides reasonable exceptions for justifiable delivery path deviations.

§ 5422. Receiving Shipments of Inventory

This proposed regulation provides the requirements that a retailer must comply with in receiving shipments of inventory of cannabis goods. The purpose of this proposed regulation is to reduce the risk of theft of cannabis goods while a retailer is accepting inventory shipments.

Subsection (a) of this proposed section clarifies that all shipments of inventory be delivered by a licensed distributor as required under Business and Professions Code section 26070, subsection (b). This proposed subsection restates the statutory requirements for clarity purposes.

Proposed subsection (b) limits the time a licensed retailer may accept shipments of inventory to between 6:00 a.m. and 10:00 p.m. Retailers face an increased risk of theft or other crime while receiving shipments between the hours of 10:00 p.m. and 6:00 a.m. This is due to the fact that it is typically darker at this time and there are fewer people out in public. By requiring retailers to avoid receiving shipments of inventory during these times, the retailers are able to reduce the risk of theft or other crime that may occur while a retailer is receiving a shipment of inventory.

Proposed subsection (c) requires that retailers receive shipments of inventory through an entryway that is not used by the public to enter or exit the premises. This reduces the risk of an individual who is not an employee of the licensee gaining access to the products that are being received by the retailer. Requiring the use of an entryway that is free of customers and other non-employee individuals reduces the risk of theft or other crime that may occur while a retailer is receiving a shipment of inventory.

§ 5423. Inventory Documentation

This proposed section provides the required inventory information that a retailer is required to document and maintain records on. The purpose of this proposed regulation is to ensure the effective use of the state track and trace system. This will in turn allow the Bureau and the other state licensing authorities to effectively track the movement of cannabis goods throughout the state. This proposed section requires that a retailer keep records of specific information for all cannabis goods in the retailer's inventory.

The information requested in subsections (a) and (b) is necessary for inventory documentation. By documenting the description of each item in the inventory and the

amount of each item, a retailer will be able to identify the items found in its inventory. Additionally, the Bureau may use this information to cross-reference with the track and trace system to verify that all the retailer's transactions and inventory levels were properly reported in the track and trace system.

The information requested in subsection (c) is required to ensure that the retailer's records are consistent with the information in the track and trace system. Subsection (d) is necessary to verify that the retailer is not carrying any items for sale that are past their sell-by or expiration date if one is provided. The information requested in subsections (e) and (f) are necessary for verifying that the information entered into the track and trace system corresponds with the retailer's inventory records.

All the information required by this section is information that will allow of the identification of all cannabis goods in the retailer's inventory as well as information for tracking the movement of all products. For the Bureau to effectively regulate its licensees, the Bureau requires accurate information regarding the movement of cannabis goods. Requiring that all retailers keep records of this inventory information and make these records available to the Bureau will assist the Bureau in effectively tracking the movement of cannabis.

§ 5424. Inventory Reconciliation

This proposed regulation provides the requirements for retailers conducting inventory reconciliation. Inventory reconciliation is necessary to verify that the retailer's inventory record is accurate. Inventory reconciliation is an effective method for identifying diversion. If, through inventory reconciliation, a retailer discovers that some amount of inventory is unaccounted for, an investigation of the possible diversion of the missing cannabis goods can begin with the goal of returning the missing cannabis goods and preventing that type of loss from occurring in the future.

Proposed subsection (a) requires that inventory reconciliation occur at least every 14 days. The reason for this requirement is that the inventory of a retailer is constantly changing because retailers continuously receive shipments of cannabis goods while selling the cannabis goods from their current inventory to customers. Regular inventory reconciliations ensure that the retailer's inventory is up-to-date, and that any indications of diversion, theft, or loss are identified early. The Bureau has determined that requiring inventory reconciliations every 14 days will allow for the early identification of evidence of diversion, theft, or loss, without being overly burdensome.

Proposed subsection (b) provides a description of what a retailer must do when conducting an inventory reconciliation. When conducting an inventory reconciliation, a retailer is required to verify that the physical inventory that they have on hand is consistent with their records pertaining to their inventory. This is important to verify that the retailer's inventory records are accurate. In order to effectively track the movement of cannabis goods through the state track and trace system, the retailer's inventory records must be accurate. This proposed regulation ensures accuracy of retail inventory records.

Proposed subsection (c) requires the retailer to retain the results of inventory reconciliations as part of the retailer's records. The proposed subsection also requires the retailer to provide such records to the Bureau upon request. This requirement would allow the Bureau to review the results of an inventory reconciliation performed even after the date the inventory reconciliation occurred.

Proposed subsection (d) requires a retailer to notify the Bureau and law enforcement if the inventory reconciliation results in evidence of theft, diversion, or loss. This is a restatement of the requirement found in Business and Professions Code section 26070, subsection (k) and Section 5036 of this division. The requirement is restated in this proposed subsection for clarity. The obligations of a retailer following the conclusion of an inventory reconciliation that yields evidence of theft, diversion, or loss appear to be appropriate for restatement in this proposed section rather than requiring a licensee to refer to both the regulations and the statutes simultaneously for the requirements in this situation.

Proposed subsection (e) requires a retailer to notify the Bureau and law enforcement if the inventory reconciliation results in evidence of theft, diversion, or loss. This is a restatement of the requirement found in Business and Professions Code section 26070, subsection (k)(1) and section 5034 of this division. The requirement is restated in this proposed subsection for clarity. The obligations of a retailer following the conclusion of an inventory reconciliation that results in a significant discrepancy in inventory appear to be appropriate for restatement in this proposed section rather than requiring a licensee to refer to both the regulations and the statutes simultaneously for the requirements in this situation.

The Act requires that retailers notify law enforcement and the licensing authority if a significant discrepancy in inventory is identified or if diversion, theft, or loss occurs. This proposed section allows a retailer to more readily identify instances of loss by requiring regular inventory reconciliations be performed by retailers.

§ 5425. Record of Sales

This proposed regulation provides the requirements for the information that must be documented for each sale of cannabis goods to a customer. The purpose of this proposed regulation is to ensure that retailers are keeping accurate records of sales transactions which would allow the Bureau to effectively track the movement of cannabis goods throughout the state. Additionally, the information required to be kept by these subsections is required for the Bureau to effectively enforce regulations regarding cannabis goods sales.

Proposed subsection (a) requires a licensed retailer to maintain an accurate record of every sale to a customer. This proposed subsection clarifies the requirement under Business and Professions Code section 26160 that every licensee keep an accurate record of commercial cannabis activity, which includes sale of cannabis goods to customers. This proposed subsection helps to eliminate any confusion as to whether a sale of cannabis goods to a customer is required to be maintained as a record.

Proposed subsection (b)(1) requires the record of sale to contain the name and employee number of the retailer employee who processed the sale. This information is necessary to

identify the employee responsible for conducting the sale transaction in case issues arise and the employee is required to be contacted by the Bureau or law enforcement for information pertaining to the transaction.

Proposed subsection (b)(2) requires the retailer to record the first name and the customer number of the customer who purchased the cannabis goods. This information is necessary to identify the customer in case issues arise and the customer is required to be contacted by the Bureau or law enforcement for information pertaining to the transaction. Assigning a customer number to each customer allows the retailer to keep a record of the transaction without having to disclose the full name of the customer.

Proposed subsections (b)(3), (b)(4), and (b)(5) require the retailer to record the date and time of the transaction, a list of all cannabis goods purchased, and the amount paid for the cannabis goods. This information is necessary to properly identify the transaction and to ensure that the movement of cannabis goods is properly being recorded by the retailer so that the information can properly be uploaded to the track and trace system. By requiring the retailer to record the amount paid for the cannabis goods, the Bureau can ensure that retailers are not providing customer with free cannabis goods in violation of the Act.

These elements are needed because the record of each sale can be used by the Bureau to monitor a retailer's activity and ensure that the retailer is following the rules regarding sales. If it becomes necessary for the Bureau to investigate a specific sales transaction for enforcement purposes, the information required by these subsections will aid the Bureau in obtaining needed information regarding the sale.

Proposed subsections (c) and (d) provide additional clarity by defining the terms "employee number" and "customer number" as used in this section. This is necessary to assure that licensees understand their responsibilities to identify employees and customers under this proposed section.

§ 5426. Records

This proposed regulation clarifies that a retailer is responsible for maintaining records in accordance with proposed section 5037 of this division. The purpose of this proposed regulation is to eliminate any confusion for retailers on how they are required to maintain their records, and is required under MAUCRSA.

§ 5427. Retailer Premises to Retailer Premises Transfer

This proposed regulation provides the requirements for a retailer transferring cannabis goods to another licensed retail premises.

Proposed subsection (a) requires that for a retail licensee to transfer cannabis goods from one licensed retail premises to another licensed retail premises, the same licensee must hold the both retail licenses. Proposed subsection (b) clarifies that when a licensee transfers cannabis goods from one retail location to another retail location, the receiving retail location may sell the cannabis goods. These proposed subsections clarify that a licensee who holds multiple retail licenses may transfer cannabis goods from one retail license to

the other. It also recognizes that licensees with multiple licensed premises may have a need to adjust the inventory at their stores to address local supply and demand.

Proposed subsection (c) clarifies that all transportation of cannabis goods under this section must comply with all the requirements regarding the transportation of cannabis goods. The purpose of this proposed subsection is to prevent licensees from conducting the transportation of cannabis goods in violation of requirements found in other section of the statutes or regulations.

Proposed subsection (d) clarifies that any cannabis goods transferred under this section be properly recorded in the track and trace system. In order to effectively track the movement of cannabis goods throughout the state, the track and trace system must be properly updated with all transactions affecting the movement of cannabis goods. The purpose of this section is to ensure that the transport of cannabis under this proposed section complies with the tracking requirements within the Act. It also ensures that the Bureau is able to review accurate records regarding the transfer of products between retail stores.

§ 5500. Microbusiness

Business and Professions Code section 26070, subdivision (a)(3) provides that the Bureau must establish a process by which an applicant for a microbusiness can demonstrate compliance with all the requirements under the Act for the activities that will be conducted under the license. This section is necessary to clarify the requirements for licensure, when an applicant seeks a microbusiness to conduct multiple commercial cannabis activities.

The Act is silent as to how many commercial cannabis activities an applicant must engage in to qualify for a microbusiness license. Subsection (a) is necessary because it clarifies that a licensee must engage in at least three of the following commercial cannabis activities: cultivation, manufacturing, distribution, and retail. This requirement is necessary to ensure that applicants are actually microbusinesses rather than using the license as a substitute for single activity licenses. This subsection is also necessary because it provides clarification to prospective microbusiness applicants regarding the premises requirements for microbusinesses engaging in manufacturing and cultivation activities.

To assure that applicants are identifying all commercial cannabis activities they wish to engage in, subsection (b) clarifies that an applicant for a microbusiness license must identify all commercial cannabis activities it wishes to engage in on its application. This requirement is necessary because it aids the Bureau's processing of the application. It also helps the Bureau maintain accurate records and ensures applicants are qualified for the type of license they are applying for.

Proposed subsection (c) is necessary to assure that all applicants applying for the requested commercial cannabis activities are supplying consistent information to the licensing entities for review. This requirement is necessary because it aids the Bureau's processing of the application. It also helps the Bureau maintain accurate records and ensures applicants are qualified for the type of license they are applying for.

Business and Professions Code section 26001, subsection (ap) defines premises as “the designated structure or structures and land specified in the application that is owned, leased, or otherwise held under the control of the applicant or licensee where the commercial cannabis activity will be or is conducted.” That section further provides that a premises shall be a “contiguous area” and shall only be occupied by one licensee. Subsection (d) is necessary to clarify that, despite conducting multiple commercial activities at one location, a microbusiness license must be tied to one licensed premises.

A microbusiness licensee may engage in multiple commercial cannabis activities. Accordingly, the Bureau recognizes the importance of all licensees complying with the regulatory framework that applies to each requested commercial cannabis activity. To that end, subsection (e) clarifies that microbusinesses that engage in distribution activities must comply with the appropriate distribution regulations; microbusinesses that engage in retail activities must comply with the appropriate retail regulations; microbusinesses that engage in cultivation activities must comply with the appropriate cultivation regulations; and microbusinesses that engage in manufacturing activities must comply with the appropriate manufacturing activities. This requirement is necessary to assure that all licensees that are conducting the same commercial cannabis activities are conducting their activities in a consistent manner.

Proposed subsection (f) recognizes that microbusiness licensees may seek to change the commercial cannabis activities they are conducting at their licensed premises. Accordingly, this subsection is necessary to clarify that when a licensee seeks to engage in additional commercial cannabis activities after the license is issued, they must submit a new application identifying the requested changes and providing all information required for an application for the commercial cannabis activity they wish to conduct. This subsection will aid the Bureau’s processing of microbusiness applications. It also assures the Bureau is able to maintain accurate records and ensures applicants are qualified for the type of license they are applying for.

Recognizing that the various commercial cannabis activities a microbusiness licensee may wish to engage in have varying security issues, subsection (g) requires microbusiness licensees to comply with the appropriate security rules and requirements applicable to the corresponding license type suitable for the activities of the licensee. This is necessary to assure that all licensees engaging in similar commercial cannabis activities are bound to the same requirements. It also assures consistency for the purposes of Bureau inspection.

Proposed subsection (h) requires that areas of the licensed premises for manufacturing and cultivation be separated from the distribution and retail areas by a wall, and that all doors between the areas remain closed when not in use. The purpose of this proposed subsection is to limit contamination and cross-exposure of cannabis goods. Cultivation and manufacturing are commercial cannabis activities involving cannabis goods that have not gone through quality assurance or testing. This proposed subsection is necessary to ensure that there are measures in place to limit and/or reduce the possibility of cannabis goods that have been tested, being contaminated or adulterated, thereby negating any testing and

testing results for cannabis goods that are available to consumers or the public, and increasing their exposure to unsafe cannabis goods.

Proposed subsection (i) clarifies that a suspension or revocation of a microbusiness license affects all commercial cannabis activities allowed pursuant to the license. This subsection is necessary to clarify that a microbusiness license's activities are not severable for the purposes of enforcement as they possess only one license.

§ 5501. Microbusiness Applications Including Cultivation Activities

In addition to the information required in section 5002 of this division, an application for a microbusiness that wishes to engage in cultivation requires additional information, consistent with the cultivation licensure requirements of the California Department of Food and Agriculture.

Subsections (a) and (b) require evidence that an applicant has been appropriately permitted by a regional water board or the State Water Resources Control Board and has performed a hazardous materials search for the cultivation site. It also requires an applicant to supply the Bureau with protocols for protecting employee safety, should the search reveal the presence of hazardous materials. These proposed regulations are added to clarify the statutory provisions in Business and Professions Code section 26051.5 and Health and Safety Code section 11362.769. These subsections are necessary for the Bureau to determine an applicant has implemented environmental protection measures sufficient to diminish the risks associated with water quality pollution by cannabis cultivation and hazardous materials. This requirement is consistent with California Department of Food and Agriculture's requirements, which are based on their review on the impacts of cannabis cultivation.

Subsections (c), (d), and (e) require the applicant to identify all power sources for indoor cultivation activities, provide a diagram of the premises, and provide a proposed cultivation plan. These proposed regulations are added to address the statutory provision in Business and Professions Code Section 26051.5 (c). In addition to the premises diagram requirements of 5006 of this division, this subsection establishes the additional requirements of the premises diagram that must be submitted with each microbusiness application that includes cultivation activities. This section is necessary to ensure the Bureau has enough detail about the premises to review and verify the premises is acceptable for licensure and to provide detailed information for compliance inspections. Cultivation plan requirements are further elaborated in section 5502 of this division, below.

Subsection (f) requires the applicant to provide at least one of the following water supply sources: retail supplier, well, rain catching system, a waterbody diversion with a water right, or a waterbody diversion with a water right exception. In addition to specifying a source, an applicant will also need to provide supplemental information about the source as detailed in Section 5503 of the proposed regulations. These proposed regulations are to clarify Business and Professions Code 26060.1 and make specific what water sources are acceptable for cultivation.

Subsection (g) requires a copy of a California Department of Fish and Wildlife (CDFW) Permit 1602, or written verification from CDFW that a streambed alteration agreement is not required, if an applicant is currently operating. These proposed regulations are added to clarify the statutory provision in BPC Section 26060.1 and ensures that the Department does not issue a license to an active cultivation site that is not compliant with Section 1602 of Fish and Game Code.

Subsection (h) requires an applicant to attest that owners are agricultural employers. This subsection is consistent with Business and Professions Code section 26051.5, subdivision (a)(8).

Subsection (i) requires an applicant for an indoor license to attest that the local fire department is aware of the cultivation site. These proposed regulations are aligned with Business and Professions Code Section 26066. The Bureau determined there were unique risks to first responders responding to indoor cultivation sites and by requiring an applicant to notify their local fire department of the presence of the site, risk would be reduced and increase safety for first responders and the public.

Subsection (j) requires an applicant for microbusiness licensure which includes cultivation activities to attest that the applicant understands that the information provided to the Bureau may be shared with the Department of Food and Agriculture for the purposes of evaluating the applicant's qualifications for licensure. This subsection is necessary to assure microbusiness cultivators are evaluated consistently with those prospective licensure applicants who are applying for cultivation licenses from the Department of Food and Agriculture. This subsection further provides that the Department of Food and Agriculture may conduct inspections of those cultivation premises related to their oversight authority.

Subsection (k) requires an applicant to provide a detailed description of any fines or penalties for cultivation or production of a controlled substance on public or private land pursuant to Fish and Game Code section 12025 or 12025.1 against the applicant within 3 years preceding the date of application. Including this information in the regulations will provide consistency and standardize the Bureau's approach to evaluating such offenses and provides a transparent process for microbusiness applicants who wish to engage in cultivation.

§ 5502. Cultivation Plan Requirements

This proposed section defines the requirements of the cultivation plan for prospective licensees who wish to engage in cultivation activities. This proposed section is necessary to specify the cultivation plan requirements for such licensees, and to assure that all prospective licensees who wish to cultivate provide consistent information to the licensing entities.

Proposed subsection (a) requires a diagram of the premises in the cultivation plan, which must outline the specific purpose of each cultivation area featured in the plan. For convenience of the prospective licensees, this section also reiterates that the total area of all cultivation activities must be less than 10,000 square feet, as required by the Act. The

cultivation plan requirements outlined by this subsection allow the Bureau to ensure compliance with the licensing requirements, which are being implemented to ensure public safety and environmental protection.

Proposed subsection (b) provides clarification on the determination of canopy. This information is critical for the Bureau's inspectors, to assure they have accurate information regarding how cultivation facilities are arranged. It also assures that all prospective microbusiness cultivators provide consistent information to the Bureau for evaluation.

Proposed subsection (c) requires a lighting diagram, including the location of lights and the maximum wattages used. This is necessary for the Bureau to ensure the appropriate license type is being issued to the applicant, and for enforcing the requirements of the specific licensee.

Proposed subsection (d) requires a pest management plan, including listing all pesticides used on cannabis at the site and any integrated pest-management protocols the applicant plans to implement. This portion of the cultivation plan is necessary for the Bureau to ensure the environment is protected from the illegal use of pesticides and ensures the licensee has a plan for handling potential pest introductions and infestations. The Bureau's requirement is consistent with the Department of Food and Agriculture's requirements. The Department of Food and Agriculture's review on the Impacts of Cannabis Cultivation discusses the risk to the environment of improper pesticide use and storage and the Department determined it was necessary to know about a licensee's pesticide use and storage plans in order to transition them into a regulated environment.

Proposed subsection (e) requires applicants to submit a cannabis waste management plan. The Bureau's requirement is consistent with the Department of Food and Agriculture's requirements. This information will help the Bureau ensure compliance with its licensing requirements, regardless of whether a cultivator disposes of waste off-site or on-site. This subsection also ensures licensees are complying with existing waste disposal laws and regulations.

§ 5503. Supplemental Water Source Information

This section details the supplemental information that an applicant must provide for each type of water source they list in their application. Subsection (a) requires applicants with retail water suppliers to provide the name of the supplier. If they are a large retail supplier such as a municipal provider, that is the extent of the information required of the applicant. If the retail water supplier has 10 or fewer customers, the applicant receives 10 percent or more of the water supplied by the retail supplier, more than 25 percent of the water delivered by the retail supplier is used for cannabis cultivation, or the applicant and the retail supplier are affiliates as defined by Section 2814.20 of Title 23 of the California Code of Regulations, then additional information is required. Applicants using these small retail suppliers will need to provide the retailer's water source and specific information regarding the location of a water diversion or well. Subsection (b) requires applicants using groundwater wells to provide location of the well and information about the well log. Subsection (c) requires applicants collecting rainwater in a catchment system to provide information about the size and storage capacity of the system. Subsection (d) requires

applicants diverting from a waterbody (lake, stream, river, etc.) to provide documentation of their right to divert water. Subsection (d) also requires applicants diverting from a waterbody and claiming an exception from the requirement to file a statement of diversion and use, to provide detailed information verifying their exception is existent. The information required for each source is necessary for the Bureau to collect to ensure each water source is verifiable by State Water Resources Control Board. This section specifies what an applicant will need to provide to the Bureau to ensure they have a complete application.

§ 5504. License Issuance in an Impacted Watershed

This section recognizes that there may be circumstances where the regional water boards, State Water Resources Control Board or the Department of Fish and Wildlife may find, based on substantial evidence, that a microbusiness' cultivation activities may cause significant adverse impacts on the environment in a watershed or geographical area. This section is necessary for the Bureau to diminish the risks associated with water quality pollution by cannabis cultivation. This section also clarifies certain scenarios where a prospective microbusiness that engages in cultivation activities may be denied for licensure. This requirement is consistent with cultivation licensure requirements of the Department of Food and Agriculture.

§ 5505. Cultivation Records for Licensees Engaging in Cultivation Activities

Business and Professions Code sections 26160 - 26162.5 requires licensees to satisfy certain records requirements. Bureau licensees must also maintain certain records pursuant to Section 5037 of the Bureau's regulations. This section makes specific additional records that microbusiness licensees engaging in cultivation activities must also keep, including:

- Cultivation plan(s).
- All records evidencing compliance with the environmental protection measures required in sections 5501, 5502, 5503, and 5504 of this division.
- All UIDs assigned to product in inventory and all unassigned UIDs. UIDs associated with product that has been retired from the track-and-trace system must be retained for six (6) months after the date the tags were retired.

Identifying the specific records to be maintained by those microbusiness licensees engaging in cultivation activities provides additional clarity to licensees. It also assures that all licensees engaging in commercial cultivation activities are maintaining similar records. The requirement that certain materials be maintained as records will aid the Bureau in enforcing these regulations, conducting investigations, and in preventing diversion and other illegal activity.

§ 5506 Microbusiness Applications Including Manufacturing Activities

In addition to the information required in section 5002 of this division, an application for a microbusiness that wishes to engage in manufacturing requires additional information, consistent with the manufacturing licensure requirements of the California Department of Public Health.

Proposed subsection (a) requires applicants to identify the type of manufacturing activity that will be conducted at the premises. This requirement is necessary because it aids the Bureau's processing of the application. It also helps the Bureau maintain accurate records and ensures applicants are qualified for the type of license they are applying for.

Proposed subsection (b) requires applicants to identify the types of products that will be manufactured, packaged, or labeled. This requirement is necessary because it aids the Bureau's processing of the application. It also helps the Bureau maintain accurate records and ensures applicants are qualified for the type of license they are applying for.

Proposed subsections (c) and (d) require applicants to identify the name, title, and phone number of the on-site individual who manages the operation of the premises, or this person's alternate. This information is necessary in case the Bureau needs to contact a person present at the facility in its capacity as a licensing authority, or in order to ensure public health and safety during the course of manufacturing activities.

Proposed subsection (e) requires applicants to identify the number of employees at the manufacturing site. This provision is necessary because it aids the Bureau in evaluating the security, inventory control, and quality control plans established by the applicant. A site with only a few employees will have different needs than a site with many employees.

Proposed subsection (f) requires applicants to provide inventory control procedures; quality control procedures; security procedures; and waste disposal procedures. This submittal requirement is reasonably necessary to aid the Bureau's review of the operations that are proposed at a prospective licensee's premises. These submittals enable the Bureau to ensure that prospective licensees have procedures in place that result in the protection of public health and safety. Specifically, established procedures may assure safe manufactured cannabis products are produced and may limit opportunities for diversion. Finally, requiring submittal of such plans is reasonably necessary to remain consistent with the manufacturing licensure requirements of the California Department of Public Health.

Proposed subsection (g) provides applicants the opportunity to claim any procedures and protocols submitted as a trade secret or confidential. The Bureau recognizes that some of the procedures or plans submitted by prospective applicants may be considered a trade secret or confidential. This provision is reasonably necessary to assure the Bureau can protect confidential information that may be communicated during the licensing process.

§ 5507 Microbusiness Records for Licensees Engaging in Manufacturing Activities

Business and Professions Code sections 26160 - 26162.5 requires licensees to satisfy certain records requirements. Bureau licensees must also maintain certain records pursuant to Section 5037 of the Bureau's regulations. This section makes specific additional records that microbusiness licensees engaging in manufacturing activities must also keep, including:

- Records related to quality of raw materials and ingredients, per section 40252 of Title 17 of the California Code of Regulations.

- Records related to manufacturing operations, per section 40254 of Title 17 of the California Code of Regulations.
- Records related to written hazard analysis, per section 40256 of Title 17 of the California Code of Regulations.
- Records related to preventative controls, per section 40258 of Title 17 of the California Code of Regulations.
- Records related to the master manufacturing protocol, per section 40262 of Title 17 of the California Code of Regulations.
- Batch production record, per section 40264 of Title 17 of the California Code of Regulations.
- Records related to product complaints, per section 40266 of Title 17 of the California Code of Regulations.
- Records related to recalls, per section 40268 of Title 17 of the California Code of Regulations.

Identifying the specific records to be maintained by those microbusiness licensees engaging in manufacturing activities provides additional clarity to licensees. It also assures that all licensees engaging in commercial manufacturing activities are maintaining similar records. The requirement that certain materials be maintained as records will aid the Bureau in enforcing these regulations, conducting investigations, and in preventing diversion and other illegal activity.

§ 5600. Cannabis Event Organizer License

Business and Professions Code Section 26200, subsection (e) allows for the issuance of a state temporary event license authorizing onsite cannabis sales to, and consumption by, persons 21 years of age or older at a county fair or district agriculture association event. The statute provides a number of requirements that apply to these licensed events. However, the statute does not provide the requirements or the process for applying for and obtaining a state temporary event license. This proposed regulation is intended to provide a portion of the process for implementing Section 26200, subsection (e).

Proposed subsection (a) of the proposed regulation clarifies that in order to obtain a temporary event license, the applicant must first obtain a cannabis event organizer license. The Bureau is required by the Act to collect certain pieces of information from every applicant for any license. Additionally, license applicants are required to comply with certain requirements, such as fingerprinting and a background check. The Bureau has also determined that a temporary event license will be required for each specific event. Rather than requiring the applicant to provide applicant information each time a temporary event license is sought, the Bureau has determined that it will be more effective to only require the applicant to provide the majority of the required applicant information during the Cannabis Event Organizer license application rather than each time the applicant plans to hold a temporary event. The following subsections of the proposed regulation provide the requirements that apply to cannabis event organizer licensees.

Proposed subsection (b) of the proposed regulation clarifies that a licensed cannabis event organizer is required to comply with a number of regulations which apply to all Bureau licensees. Business and Professions Code Section 26200, subsection (e) requires that the activities under a licensed cannabis temporary license are consistent with the regulations promulgated by the Bureau. As a Bureau licensee, a cannabis event organizer is required to comply with all requirements for all Bureau licensees. Many of these requirements are found in Chapter 1 of the proposed regulations. However, there are some requirements found in regulations that would not logically apply to a cannabis event organizer licensee. For example, proposed sections 5001 and 5002 contain the requirements for a temporary and annual application respectively. Since the specific application requirements for a cannabis event organizer can be found in this proposed section, an applicant for an event organizer license would not need to follow the requirements in section 5001 and 5002. This proposed subsection identifies the regulation sections in Chapter 1 that an event organizer applicant does not have to comply with.

Proposed subsection (c) of the proposed regulation clarifies that a cannabis event organizer license does not authorize a cannabis event organizer to engage in any other commercial cannabis activity aside from organizing cannabis events. The purpose of this section is to eliminate any confusion as to whether a cannabis event organizer licensee may engage in other commercial cannabis activity under the event organizer license.

Proposed subsection (d) clarifies that a licensed cannabis event organizer is required to comply with all the record retention provisions in proposed section 5037 of this division. The purpose of this proposed subsection is to eliminate any risk of misunderstanding on the part of a licensed cannabis event organizer as to what type of records they must maintain and how they are required to maintain those records. There is no reason why event organizer licensees should have different record retention requirements from other types of licensees. This proposed subsection also notifies event organizer licensees that they may be subject to discipline for violations of the Bureau's record retention requirements.

Proposed subsection (e) is necessary for application processing. Permitting online submission provides flexibility for the applicant to submit the application from anywhere in the State. The State of California is very large and requiring an applicant to physically turn in hard copies in person in Sacramento would be tremendously burdensome on the applicant and the burgeoning industry. Permitting applicants to submit electronically also helps the Bureau process the applications in an effectively and timely fashion.

Proposed subsection (f) would specify that applicants that wish to apply online must first register for a user account by doing the following: 1) creating a user name, password, and security question and answer; 2) provide an email address; and 3) provide the owner's first and last name, primary phone number, social security number or individual taxpayer identification number, date, and mailing address. These items are necessary to identify the applicant.

Proposed subsections (g)(1) through(g)(3) would specify that the applicant must provide the name of the applicant, the DBA of the applicant, and lastly must pay the application fee

in proposed section 5014. These items are necessary to identify the applicant's legal business identity and to clarify that payment of the application fee is necessary at the time the application is submitted.

Proposed subsections (g)(4) would allow an owner that is serving or has previously served in the military to disclose their service and receive expedited application processing if the owner can provide evidence of honorable discharge. This optional disclosure applies to all Department of Consumer Affairs boards and Bureaus, which includes the Bureau, through Business and Professions Code section 115.4 and is included here for clarity.

Proposed subsections (g)(5) and (g)(6) would require the applicant to identify the license types, license numbers, the date the license was issued, and which licensing authority issued the license for any licenses the applicant holds from the Bureau and all other state licensing authorities. The applicant would also be required to disclose whether the applicant has been denied a license or had one revoked or suspended by the Bureau or any other state cannabis licensing authority. These subsections are necessary to ensure that the granting of a license would not violate the provision in Business and Professions Code section 26053, subdivision (b) prohibiting a person that holds a state testing laboratory license from receiving any other type of cannabis license. It is also necessary for the Bureau to know if a license has ever been denied, revoked, or suspended as these could be grounds for denial of the application.

Proposed subsection (g)(7) through (g)(10) would require specific contact information for the cannabis business including the mailing address, the telephone number for the premises, the website address, and email address. These items are necessary to contact the premises. Further, they are necessary for monitoring the cannabis business once it is licensed to ensure the business is complying with laws and regulations.

Proposed subsection (g)(11) would require an applicant to provide contact information for the applicant's designated primary contact person including the name, title, telephone number, and email address if applicable. This information is necessary so that the Bureau knows who to contact regarding questions or issues with an application or license.

Proposed subsections (g)(12) through (g)(18) would require the applicant to provide the business' federal employer identification number, the business' organizational structure, the business-formation documents, a list of all fictitious business names the applicant is operating under, the certificate of qualification if the applicant is a foreign corporation, financial information, and, as required by Business and Professions Code section 26051.5, subdivision (d), a list of every individual who has a financial interest. This information is necessary to identify the applicant and to enable the Bureau to determine how the commercial cannabis business will be organized and to ensure that all owners as defined in proposed section 5003 and all financial interest holders in proposed section 5004 are identified.

In order for the Bureau to conduct a thorough and effective evaluation of an applicant's submission, to ensure the applicant is a bona fide and qualified applicant under the law, the Bureau must receive specific information from the applicant. The information contained in

proposed subsection (g)(19)(A) through (N) are necessary for the Bureau to accurately determine and verify the true identity of individual owners as defined in proposed section 5004.

Under Business and Professions Code sections 144; 26051.5, subsection (a)(1) the Bureau is required to request and conduct criminal history record checks on all applicants. The information contained in proposed subsection (g)(19)(L)(i) – (vi) clarifies what information is needed by the Bureau in order to gather all pertinent criminal history information in order to properly conduct the statutorily mandated checks.

Proposed subsection (g)(20) would require that an applicant with 20 or more employees attest that the applicant has entered into a labor peace agreement and will abide by the terms of the agreement and provide a copy of the agreement to the Bureau or, if they have not yet entered into such an agreement, then provide a notarized statement indicating that the applicant will enter into and abide by the terms of a labor peace agreement. This subsection is necessary to fulfill the statutory requirements of Business and Professions Code section 26051.5(a)(5). The Bureau has further clarified the statutory requirements by requiring the applicant provide a copy of the signature page of the labor peace agreement or a notarized statement that they will enter into one. The Bureau determined that the additional requirements were necessary to ensure that applicants are aware of the requirement and have taken steps to fulfill the requirement. This is necessary to protect the public, which includes workers in the cannabis industry, is the highest priority under the Act so the Bureau must ensure that applicants are prepared to comply with labor standards and protect their employees' rights.

Proposed subsection (g)(21) would require that applicant's provide a limited waiver of sovereign immunity if applicable as required under proposed section 5009. This requirement is repeated in the application for clarity so that applicants may have all the required materials for an application listed in one section.

§ 5601. Temporary Cannabis Event License

Business and Professions Code Section 26200, subsection (e) allows for the issuance of a state temporary event license authorizing onsite cannabis sales to, and consumption by, persons 21 years of age or older at a county fair or district agriculture association event. The statute provides a number of requirements that apply to these licensed events. However, the statute does not provide the requirements or the process for applying for and obtaining a state temporary event license. This proposed regulation is intended to provide a portion of the process for implementing Section 26200, subsection (e).

Subsection (a) of the proposed regulation clarifies the authority granted to a licensee who holds a temporary cannabis event license. This proposed subsection specifies that a licensee who holds a temporary cannabis event license may hold a temporary cannabis event where the onsite sale and consumption of cannabis goods is authorized at the location indicated on the license during the dates indicated on the license. The purpose of this proposed subsection is to provide a general description of what activities a temporary cannabis event

licensee may engage in. Additionally, the proposed subsection indicates that the activities under a temporary cannabis event license are limited to the identified locations and during the dates indicated on the license. The purpose of this proposed subsection is to eliminate any confusion as to where and when a temporary cannabis event licensee may hold a temporary cannabis event.

Proposed subsection (b) clarifies that only a licensed cannabis event organizer may obtain a temporary cannabis event license. The Bureau has also determined that a temporary event license will be required for each specific event. Rather than requiring the applicant to provide applicant information each time a temporary event license is sought, the Bureau has determined that it will be more effective to only require the applicant to provide the majority of the required applicant information during the cannabis event organizer license application process, rather than each time the applicant plans to hold a temporary event. A cannabis event license is valid for up to one year. However, a temporary cannabis event license is only valid for the dates of the temporary cannabis event. The Bureau has determined that it will be most effective to require the cannabis event organizer obtain an organizer license which may be renewed annually and then obtain a separate temporary cannabis event license for each event the organizer plans to hold. This would eliminate the need for the submission of duplicative information. Information for the event organizer would be collected at the time of the event organizer application and information for the specific events would be collected at the application for each temporary cannabis event license.

Proposed subsection (c) clarifies that a violation of the requirements for a temporary cannabis event may result in disciplinary action against the licensees responsible for the violation as well as the licensed cannabis event organizer. The purpose of this proposed subsection is to put the event organizer on notice that they are responsible for ensuring that all activities occurring at the temporary cannabis event comply with the requirements found in the regulations. This will hopefully result in fewer violations of the rules as the cannabis event organizer will be motivated to make an extra effort to ensure that all licensees are following the rules during the temporary cannabis event.

Proposed subsection (d) clarifies that a temporary cannabis event license may only be obtained for a single day or consecutive days. The Bureau has determined that holding a temporary cannabis event on non-consecutive days would require the event organizer to obtain separate temporary event licenses. Additionally, this proposed subsection limits temporary cannabis events to 4 consecutive days. The Bureau has determined that 4 days is the maximum amount of days that will be allowed for a temporary event license as these are meant to be short events, not permanent arrangements.

Proposed subsection (e) requires that an applicant for a temporary cannabis event submit the application to the Bureau at least 60 days prior to the event. The purpose of this proposed subsection is to provide the Bureau with enough time to conduct a comprehensive review of the application prior to the date of the event. The Bureau has determined that 60 days prior to the event is an appropriate amount of time.

Proposed subsection (f) clarifies where a temporary cannabis event may take place. Business and Professions Code Section 26200, subsection (e), which provides the authority for the temporary event license, states that a temporary event license authorizes onsite cannabis sales and consumption by person 21 or older at a county fair or district agricultural association event. The purpose of this proposed subsection is to clarify the meaning of the terms “county fair or district agricultural association event,” as used in the statute. The Bureau has interpreted these terms to mean that the temporary cannabis events must take place on the specific locations of the county fairs or district agricultural association events.

Proposed subsection (g) prohibits the issuance of a temporary cannabis event license if the premises to be licensed is licensed for the sale of alcohol or tobacco. Business and Professions Code Section 26200 requires that the location of the temporary cannabis event does not allow the sale or consumption of alcohol or tobacco on the premises. This proposed subsection restates this requirement for clarity.

Proposed subsection (h) provides the requirements for an application for a temporary cannabis event license. The purpose of this proposed subsection is to clarify what information an applicant must submit as part of the application. Proposed subsection (h)(1)-(h)(4) requires the applicant to provide identifying information such as the name of the applicant, the license number for each license held by the applicant, the address of the location of the event, and the name of the event. All of this information is required so the Bureau can identify the applicant and the event that they are seeking to license. Proposed subsection (h)(5) requires the applicant to provide a diagram of the physical layout of the event, including the locations where cannabis goods will be sold, consumed, and stored. This information is important to the Bureau because the diagram can be used to ensure that the applicant will be complying with all of the requirements pertaining to the physical layout of the event. Proposed subsection (h)(6) requires the applicant to provide the dates of the event for which they are seeking a temporary cannabis event license. This information is important so that the Bureau will know what dates the license will be issued for. Proposed subsection (h)(7) requires the applicant to provide contact information for the designated primary contact for the temporary event license. This information is important so that the Bureau will be easily able to communicate with the licensee. Proposed subsection (h)(8) requires the applicant to provide contact information for a contact person who will be onsite at the event and reachable at the time of the event. This information is necessary for the Bureau to be able to contact the licensee during the event. There are many potential reasons for why the Bureau may need to contact a representative of the licensee who is onsite while the event is taking place. Proposed subsection (h)(9) requires the applicant to provide the Bureau with a waste management plan that complies with the requirements for a waste management plan in proposed subsection 5002 of this division. This information is required so that the Bureau will be able to verify that any cannabis waste generated by the event will be properly disposed of prior to issuing a license for the event. Proposed subsection (h)(10) requires the applicant to provide documentation of the approval from the local jurisdiction to hold the temporary cannabis event. Business and

Professions Code Section 26200 requires authorization from the local jurisdiction in order to obtain a temporary cannabis event license from the Bureau. Proposed subsection (h)(11) requires the applicant to provide a list of all of the licensed retailers and employees who will be engaging in the sale of cannabis goods at the event. This information is important in order for the Bureau to properly verify that all retailers who are planning on providing cannabis goods for sale at the event are properly licensed by the Bureau to engage in this activity. This information is also important because Bureau enforcement staff will be able to identify the retailers and employees that will be participating in the event. Proposed subsection (h)(12) requires the applicant to attest that the information is true. Business and Professions Code Section 26051.5 requires that any applicant for a license from the Bureau provide this type of attestation.

Proposed subsection (i) requires a temporary cannabis event licensee to provide notice to the Bureau if the list of retailers and employees who will be selling cannabis goods at the event changes. This proposed subsection requires that the licensee provide this information to the Bureau at least 72 hours before the event begins to allow the Bureau to confirm the participants are licensed before the event. This information is required for the Bureau to be able to accurately identify the retailers and employees that will be participating in the event and for the Bureau to be able to ensure that all retailers of cannabis goods at the event are properly licensed.

Proposed subsection (j) requires temporary cannabis event licensees to hire or contract for security personnel to be present at the temporary cannabis event premises at all times cannabis goods are sold or being consumed. This proposed subsection is intended to increase public safety by requiring that security personnel be present at the temporary cannabis event. The presence of security personnel is expected to reduce the risk of theft and other crimes that may take place during these events. The proposed subsection also requires that security be properly licensed under state law.

Proposed subsection (k) requires the temporary cannabis event licensee to post signs indicating that areas in which cannabis goods are sold or consumed are limited to persons 21 or older. The purpose of this proposed subsection is to reduce the exposure of minors to cannabis goods by clearly indicating to the public that only certain persons can enter these areas and preventing minors from accessing these areas.

Proposed subsection (l) requires all licensees to comply with the cannabis waste disposal requirements found in the regulations. The waste disposal requirements already apply to all licensees. However, the requirements are restated in this proposed subsection in to clarify that waste disposal requirements apply to temporary cannabis events. Additionally, this proposed subsection allows a cannabis event organizer to arrange for or contract for the proper disposal of all cannabis waste generated by the temporary cannabis event. This proposed subsection provides for an option to dispose of cannabis waste generated at the event collectively rather than requiring each individual licensee to dispose of cannabis waste individually. The purpose of providing this option was to allow for more efficient methods of waste disposal.

Proposed subsection (m) requires all licensees that are involved in the temporary cannabis event to comply with the record keeping requirements found in the Act and the regulations. All licensees are already required to comply with record keeping requirements. This requirement is restated in this proposed subsection to clarify that the record keeping requirements also apply to temporary cannabis events.

§ 5602. Temporary Cannabis Event Sales

Business and Professions Code Section 26200, subsection (e) allows for the issuance of a state temporary event license authorizing onsite cannabis sales to, and consumption by, persons 21 years of age or older at a county fair or district agriculture association event. The statute provides a number of requirements that apply to these licensed events. However, the statute does not provide the specific requirements for the sale of cannabis goods at these temporary cannabis events. This proposed regulation is intended to provide the specific requirements for sale of cannabis goods at temporary cannabis events.

Proposed subsection (a) indicates that only persons 21 or older may purchase cannabis goods at a temporary cannabis event. This requirement is found in the Act. The requirement is restated here for clarity. Additionally, the proposed subsection requires a licensee who is selling cannabis goods at a temporary cannabis event to confirm the age and identity of the customer. The purpose of this proposed subsection is to limit or exposure of cannabis to minors by ensuring that cannabis goods sold at temporary cannabis events are only sold to persons who are of the proper age.

Proposed subsection (b) requires that all sales of cannabis goods occur in the retail area as identified in the diagram provided to the Bureau as part of the temporary cannabis event application. This is important in order for the Bureau to be able to ensure that all sales of cannabis goods at temporary events comply with the requirements. If cannabis goods sales are allowed to occur in areas outside of the designated retail area, it would be much more difficult for the Bureau and the event organizer to ensure that all sales comply with the requirements.

Proposed subsection (c) requires that all sales of cannabis goods at a temporary cannabis event be conducted by a licensed retailer or a microbusiness that is authorized to engage in the retail sale of cannabis. This subsection is necessary to clarify who can engage in the sale of cannabis goods at a temporary cannabis event. The Bureau has determined that since licensed retailers have been deemed to meet the requirements to sell cannabis goods to customers on their licensed premises, only licensed retailers may sell at a temporary cannabis event. Allowing licensed retailers, who have already been approved to engage in retail sales, to sell at temporary events is more economical than requiring persons who plan to sell at the event to undergo a separate licensing process for each individual event. The proposed subsection also clarifies that a licensed cannabis event organizer may sell cannabis goods at a temporary cannabis event only if the event organizer also holds a retail license. This is intended to eliminate any confusions as to when an event organizer may or may not engage in the sale of cannabis goods at a temporary cannabis event. Proposed subsection (c) also clarifies that all retailers or licensed microbusinesses shall only conduct

their sales activities within their specifically assigned area, identified in the diagram of the physical layout of the temporary cannabis event; mobile sales activities via wagon, cart, or similar means are prohibited. This requirement is necessary because it enables the Bureau to ensure that all sales of cannabis goods at temporary events comply with the requirements. If cannabis goods sales are allowed to occur in areas outside of the licensee's specifically assigned area, it would be much more difficult for the Bureau and the event organizer to ensure that all sales comply with the requirements.

Proposed subsection (d) requires retailers and microbusinesses to prominently display their temporary cannabis event location number and state license within plain sight of the public. This requirement will allow any agency representative on a routine inspection to readily determine validity of a license. This protocol is widely utilized by licensing agencies for many varieties of licenses. This section is necessary to clarify the Bureau's license expectations – requiring a licensee to post their license and to provide the licensing entities and prospective patrons consistency in their ability to verify state licensure.

Proposed subsection (e) requires that all sales of cannabis goods at a temporary cannabis event take place during the dates indicated on the temporary event license. Additionally, this proposed subsection requires that all sales of cannabis goods at a temporary event comply with the hours of operation requirements in proposed section 5403. This provision is important because the temporary event license only authorizes the sale of cannabis goods during the specific period provided on the license. Any sales that occur outside of that time would be unlicensed. Additionally, this proposed subsection clarifies that the hours of operation requirements that apply to the retail sale of cannabis would also apply to sale that occur during a temporary cannabis event.

Proposed subsection (f) prohibits the sale and consumption of alcohol or tobacco on the temporary cannabis event premises. This requirement is found in Business and Professions Code Section 26200. The requirement is restated in this proposed subsection for clarity.

Proposed subsection (g) requires that all cannabis goods for sale at the temporary cannabis event comply with the requirements for the transportation of cannabis goods found in the act and the regulations. The purpose of this proposed subsection is to clarify that transportation requirements apply to cannabis goods being transported to temporary cannabis events. This subsection also requires cannabis goods intended for sale be checked by the event organizer to prevent prohibited items, such as alcohol and tobacco, from entering the licensed premises to protect public safety.

Proposed subsection (h) requires that all cannabis goods that are not being used for display at a temporary cannabis event be stored in a secure, locked container. The proposed subsection also requires that cannabis events being stored at a temporary cannabis event not be left unattended. The purpose of this proposed subsection is to reduce the risk of theft or diversion of cannabis goods. By limiting the amount of cannabis goods that are readily available and requiring cannabis goods to be stored in a locked container, the risk of theft of cannabis goods during the event will be reduced.

Proposed subsection (i) requires that all cannabis goods for sale at the temporary cannabis event comply with the requirements for the laboratory testing of cannabis goods found in the act and the regulations. The purpose of this proposed subsection is to clarify that laboratory testing requirements apply to cannabis goods being sold at temporary cannabis events.

Proposed subsection (j) requires that all cannabis goods for sale at the temporary cannabis event comply with the track and trace system requirements found in the act and the regulations. The purpose of this proposed subsection is to clarify that the track and trace system requirements apply to cannabis goods being sold at temporary cannabis events.

Proposed subsection (k) requires that all cannabis goods for sale at the temporary cannabis event comply with the requirements for the display of cannabis goods found in the act and the regulations. The purpose of this proposed subsection is to clarify that the display requirements apply to cannabis goods being sold at temporary cannabis events.

Proposed subsection (l) requires that all cannabis goods for sale at the temporary cannabis event comply with the requirements for exit packaging as found in proposed section 5413 and the Act. The purpose of this proposed subsection is to clarify that exit packaging requirements apply to cannabis goods being sold at temporary cannabis events.

Proposed subsection (m) requires that all cannabis goods returned by customers at the temporary cannabis event comply with the requirements for customer returns of cannabis goods found in the act and the regulations. The purpose of this proposed subsection is to clarify that the return requirements apply to cannabis goods being sold and returned at temporary cannabis events.

Proposed subsection (n) requires that all cannabis goods for sale at the temporary cannabis event comply with the daily sales limits found in the act and the regulations. The purpose of this proposed subsection is to clarify that the daily sales limits apply to cannabis goods being sold at temporary cannabis events.

Proposed subsection (o) requires that all cannabis goods for sale at the temporary cannabis event comply with the requirements for the laboratory testing of cannabis goods found in the act and the regulations. The purpose of this proposed subsection is to clarify that laboratory testing requirements apply to cannabis goods being sold at temporary cannabis events.

Proposed subsection (p) clarifies that the licensed event organizer may also be held responsible for any violations by the retailers participating in the event. The purpose of this proposed subsection is to reduce the risk of violations by motivating the licensed event organizer to ensure that the retailers who are participating in the event comply with all the rules. This is likely to be effective as the event organizer will likely be present at the event and be in good position to monitor and correct the behavior of the retailers who are participating.

Proposed subsection (q) prohibits an event organizer from receiving compensation, that is tied to the sale of cannabis goods, from a retailer who is participating in the temporary event. The purpose of this proposed subsection is to prevent an event organizer from unwittingly engaging in the unlicensed sale of cannabis goods. An organizer who receives compensation based on the amount of cannabis goods sold by a retailer may, at some point, be considered to be engaging in the sale of cannabis goods themselves. In order to prevent this from happening compensation based on the sale of cannabis goods is prohibited.

§ 5603. Temporary Cannabis Event Consumption

Business and Professions Code section 26200, subsection (e) allows for the issuance of a state temporary event license authorizing onsite cannabis sales to, and consumption by, persons 21 years of age or older at a county fair or district agriculture association event. The statute provides a number of requirements that apply to these licensed events. However, the statute does not provide the specific requirements for the consumption of cannabis goods at these temporary cannabis events. This proposed regulation is intended to provide the specific requirements for the consumption of cannabis goods at temporary cannabis events.

Proposed subsection (a) limits access to the cannabis consumption area to persons 21 or older. This requirement is found in Business and Professions Code section 26200. The requirement is restated in this proposed subsection for clarity.

There are specific requirements for the consumption of cannabis at these events. To effectively monitor the consumption of cannabis at the event, all consumption must be limited to a designated area, as indicated on the premises diagram required under proposed section 5602. Proposed subsection (b) requires that cannabis consumption is not visible from a public place or a non-age restricted area. This requirement is found in Business and Professions Code section 26200. The requirement is restated in this proposed subsection for clarity. Proposed subsection (c) prohibits the consumption of alcohol or tobacco in the consumption area. This requirement is found in Business and Professions Code section 26200. The requirement is restated in this proposed subsection for clarity.

Proposed subsection (d) requires that all local requirements for the consumption of cannabis be followed. This requirement is found in Business and Professions Code section 26200. The requirement is restated in this proposed subsection for clarity and also clarifies that smoking of cannabis goods is prohibited where smoking is prohibited by law. This will eliminate any confusion as to where smoking cannabis goods is allowed.

Proposed subsection (e) clarifies that the licensed event organizer may also be held responsible for any violations occurring at the event. The purpose of this proposed subsection is to reduce the risk of violations by motivating the licensed event organizer to ensure that cannabis consumption at the event complies with the requirements. This is likely to be effective as the event organizer will likely be present at the event and be in a good position to monitor and correct issues that may arise during the course of the event.

Proposed subsection (f) clarifies that the cannabis event organizer and all other licensees participating in a temporary cannabis event are required to follow all applicable requirements pertaining to recordkeeping and waste management. All licensees are already required to comply with record keeping and waste requirements. This requirement is restated in this proposed subsection to clarify that the record keeping, and waste requirements also apply to temporary cannabis events.

Proposed subsection (g) clarifies that any compensation paid from a licensed retailer to a cannabis event organizer for participation in a temporary cannabis event shall not be determined based on, or tied to, the sale of cannabis goods. This requirement assures that cannabis event organizers do not develop a financial interest or ownership interest in participating licensees that has not been disclosed to the Bureau.

§ 5700. Definitions

Proposed subsection (a) defines “acceptance criteria” as the specified limits placed on characteristics of an item or method that are used to determine data quality. This definition is necessary because acceptance criteria are parameters defined in standard operating procedures and are compared with certain measures (such as precision, accuracy, representativeness, comparability, and completeness) to determine the validity of collected data.

Proposed subsection (b) defines “accredited college or university” as a college or university accredited by a regional or national accrediting agency that is an accreditor recognized by the Secretary of the United States Department of Education. This definition is necessary to clarify requirements for testing laboratory personnel to ensure they are competent in performing analytical testing and related tasks. The Department of Education (Department) provides oversight over the postsecondary accreditation system through its review of all federally recognized accrediting agencies. The department holds accrediting agencies accountable by ensuring that they enforce their accreditation standards effectively. Also, as a part of the Department’s oversight roles, the Secretary of Education is required by law to publish a list of nationally recognized accrediting agencies that the Secretary determines to be reliable authorities as to the quality of education or training provided by the institutions of higher education and the higher-education programs they accredit. This proposed section is also necessary to distinguish between an unaccredited college or university and an accredited one.

Proposed subsection (c) defines “accreditation body” as an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing. This definition is necessary to clarify requirements for testing laboratories to become accredited from an accrediting body.

This will allow for improved quality of the data and ensure the laboratories are accountable for their test results.

Proposed subsection (d) defines “action level” as the threshold value that provides the criterion for determining whether a sample passes or fails an analytical test. It is a common term in regulatory schemes and is necessary for setting the limitation criteria for various laboratory tests.

Proposed subsection (e) defines “analyte” as a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured. This definition clarifies what is considered an analyte for testing purposes.

Proposed subsection (f) defines “analytical batch” as a set of no more than 20 samples that is prepared together for the same analysis and are prepared with laboratory quality control (LQC) samples. A batch of 20 samples is standard in environmental testing laboratories, as mandated by EPA methods, such as EPA method 538 for the determination of pesticides in drinking water. This definition enables the regulated public to distinguish between an analytical batch and other “batches” as that word is used elsewhere in the regulations. Analytical batches contain quality control samples as required in these proposed regulations.

Proposed subsection (g) defines “analytical method” as a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample. This definition is necessary because a laboratory must create standard operating procedures for all analytical methods the laboratory performs, as required in these proposed regulations.

Proposed subsection (h) defines “analytical sequence” as a group of samples that are analyzed sequentially using the same instrument calibration curve. This definition is necessary to provide clarity to the regulated public and to clarify the differentiation between an analytical sequence and an analytical batch.

Proposed subsection (i) defines “cannabinoid” as a class of diverse chemical compounds that is derived from a cannabis plant. This is necessary to identify the chemical compounds that together comprise the pharmacologically active ingredients in cannabis goods. While Business and Professions Code section 26120(c)(1)(5) refers to cannabinoids as the pharmacologically active ingredients, the statute does not specifically define the term.

Proposed subsection (j) defines “CAS number” as the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service, a division of the American Chemical Society. Using CAS numbers allows for a reliable reference to a specific substance. This is necessary for clarity because many substances have various names and because disciplines use different names for the same substance.

Proposed subsection (k) defines “CBD” as cannabidiol, Chemical Abstracts Service number 13956-29-1. This definition is necessary to identify the unique numerical identifier and name of this cannabinoid, as known in the scientific community, for which chemical testing may be required. This definition is necessary to ensure the regulated community has the same understanding of what this substance is.

Proposed subsection (l) defines “CBDA” as cannabidiolic acid, Chemical Abstracts Service number 1244-58-2. This definition is necessary to identify the unique numerical identifier and name of this cannabinoid, as known in the scientific community, for which chemical testing may be required. This definition is necessary to ensure the regulated community has the same understanding of what this substance is.

Proposed subsection (m) defines “CBG” as cannabigerol, Chemical Abstracts Service number 25654-31-3. This definition is necessary to identify the unique numerical identifier and name of this cannabinoid, as known in the scientific community, for which chemical testing may be required. This definition is necessary to ensure the regulated community has the same understanding of what this substance is.

Proposed subsection (n) defines “CBN” as cannabinol, Chemical Abstracts Service number 521-35-7. This definition is necessary to identify the unique numerical identifier and name of this cannabinoid, as known in the scientific community, for which chemical testing may be required. This definition is necessary to ensure the regulated community has the same understanding of what this substance is.

Proposed subsection (o) defines “certificate of accreditation” as a document issued by an accreditation body that attests to the laboratory’s competence to carry out specific testing analysis. This definition specifies the requirement of laboratories to obtain a certificate of accreditation from their chosen accrediting body to ensure compliance with the proposed regulations.

Proposed subsection (p) defines “certificate of analysis” (COA) as the report prepared by the laboratory about the analytical testing performed and results obtained by the laboratory. COA is used in the enabling statute, and this definition specifies what that document is.

Proposed subsection (q) defines “certified reference material” as a reference material prepared by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation. Preparation and analysis of a certified reference material sample is a necessary component of quality control procedures when conducting sample analysis; therefore, clarifying this term is necessary.

Proposed subsection (r) defines “chain of custody” (COC) as the chronological documentation that records the sequence of custody, control, transfer, analysis, and disposition of a sample. This definition is necessary to specify the required chain of

custody protocol that will serve as documentation for the integrity of the samples from collection through destruction by a licensed testing laboratory.

Proposed subsection (s) defines “coefficient of determination” denoted r^2 , as a statistical measure that determines how well the regression approximates the actual data points, with a regression of 1 being a perfect fit. The coefficient of determination is a necessary component of quality control procedures, as it is related to calibration, when conducting sample analysis; therefore, clarifying this term is necessary.

Proposed subsection (t) defines “continuing calibration verification” (CCV) as a type of quality control sample that is a mid-range calibration standard which checks the continued validity of the initial calibration of the instrument. The CCV is a necessary component of quality control procedures when conducting sample analysis; therefore, clarifying this term is necessary.

Proposed subsection (u) defines “corrective action” as an action to resolve the cause of noncompliance with a requirement, standard, or procedure and prevent the recurrence of the same or similar cause of nonconformance. There can be more than one cause for a nonconformity and corrective action is taken to prevent recurrence. Corrective actions are a necessary component of the laboratory quality assurance program; therefore, clarifying this term is necessary.

Proposed subsection (v) defines “exclusivity” as the specificity of the test method for validating microbial testing methods. Exclusivity measures the ability of the method to distinguish the target organisms from similar, but genetically distinct, non-target organisms. Exclusivity is the specificity of the microbiological method used (i.e. the percentage of non-target samples that give the correct negative result). “Similar but genetically distinct” refers to target organisms/DNA from the same genus, but different strains or species. For example, a method used for the detection of *Aspergillus fumigatus* should be exclusive of other related species and non-related genera, such as *Aspergillus niger* or *Penicillium verrucosum*.

Proposed subsection (w) defines “foreign material” as any filthy, putrid, or decomposed substance including hair, insects, excreta, or related adulterant that may be hazardous or cause illness or injury to the consumer. This definition is necessary to ensure the regulated community has the same understanding of “foreign material” to properly perform the analysis.

Proposed subsection (x) defines “frequency” as the number of items occurring in each category. Frequency may be determined by analytical method or laboratory specific requirements for accuracy, precision of the analysis, or statistical calculation. This definition is necessary for testing laboratories when developing their standard operating procedures and quality control acceptance criteria.

Proposed subsection (y) defines “inclusivity” as the sensitivity of the test method related to microbiological method validation. Inclusivity measures the ability of the test method to detect a wide range of target organisms by a defined relatedness. Inclusivity is the sensitivity of the microbiological method used (i.e. the percentage of target samples that give the correct positive result). “Defined relatedness” refers to target organisms/DNA that are genetically related under a single genus, species, or strain. For example, a laboratory uses a method for the detection of Shigatoxigenic Escherichia coli (STEC), to the laboratory should ensure that it is inclusive of each of the different STEC strains, such as strains O157, O26, O145, etc.

Proposed subsection (z) defines “inhalable” as consumable in gaseous or vapor form through the lungs. This definition is necessary to ensure the regulated community has the same understanding of what “inhalable” means.

Proposed subsection (aa) defines “initial calibration verification” (ICV) as a solution of method analytes of known concentration that is obtained from a source external to the laboratory and different from the source of calibration standard. An initial calibration verification is necessary to verify the validity and accuracy of the standards used in the calibration curve.

Proposed subsection (bb) defines “ISO/IEC” as the joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission. This definition is necessary to clarify the meaning of ISO/IEC as used in the Act at Business and Professions Code section 26100(g).

Proposed subsection (cc) defines “ISO/IEC 17025” as the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories. This definition is necessary to clarify the meaning of ISO/IEC as used in the Act at Business and Professions Code section 26100(g).

Proposed subsection (dd) defines “ISO/IEC 17034” as the general requirements established by the ISO/IEC for the competence of reference material producers. This definition is necessary because reference materials are required to be used by the testing laboratories.

Proposed subsection (ee) defines “ISO/IEC 17043” as the general requirements established by the ISO/IEC for proficiency testing. This definition is necessary because testing laboratories are required to participate in proficiency testing.

Proposed subsection (ff) defines “laboratory” as a “testing laboratory” as defined at Business and Professions Code section 26001(at).

Proposed subsection (gg) defines “Laboratory Control Sample” (LCS) as a blank matrix to which known concentrations of the method analytes are added in the laboratory. The LCS is analyzed exactly like a sample and its purpose is to determine whether the methodology

is in control and whether the laboratory can make accurate and precise measurements. Preparation of an LCS sample is a necessary component of quality control procedures, and providing the definition lends clarity to the regulations.

Proposed subsection (hh) defines “laboratory replicate sample” as a second sub-sample taken from the representative sample during sample preparation and analyzed in an identical manner to the first sub-sample. The results from replicate analyses are used to evaluate analytical precision. Analyzing a laboratory replicate sample per analytical batch is standard procedure in environmental test methods. Preparation of a laboratory replicate sample is a necessary component of quality-control procedures, and providing the definition lends clarity to the regulations.

Proposed subsection (ii) defines “laboratory employee” as any person directly employed by the laboratory for wages, salary, barter, or trade. Laboratory employee does not mean independent contractor, third party entity or any other entity acting on behalf of the laboratory. This definition is necessary to ensure the regulated community has the same understanding of the definition of the term “laboratory employee.”

Proposed subsection (jj) defines “laboratory quality assurance” as the set of operating principles that enable laboratories to produce defensible data of known accuracy and precision. Laboratory quality assurance includes employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things. This definition is necessary to distinguish laboratory quality assurance from “quality assurance” because laboratory quality assurance ensures the production accurate and precise data. Note that this definition is not the same as the one for as applies to distributors in the MAUCRSA. Rather, “quality assurance” as used in this chapter is the commonly used term used in laboratory setting.

Proposed subsection (kk) defines “limit of detection” (LOD) as the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit. This definition is commonly used in the laboratory testing industry, and providing the definition brings clarity to the regulations. Reporting the limit of detection is a necessary component of method validation as well as quality control procedures when conducting sample analysis.

Proposed subsection (ll) defines “limit of quantitation” (LOQ) as the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision. This definition is commonly used in the laboratory testing industry and providing the definition buys clarity to the regulations. Reporting the limit of quantitation is a necessary component of method validation as well as quality control procedures.

Proposed subsection (mm) defines “matrix” as the substances that are present in a sample except for the analyte(s) of interest. Matrices in the cannabis field include dried flower, hashish, kief, wax, shatter, oil, edible cannabis products, and other cannabis goods. The definition is necessary to provide clarity to the regulated community.

Proposed subsection (nn) defines “matrix spike sample” as a sample prepared by adding a known quantity of the target analyte to a sample matrix or to a matrix that is as closely representative of the matrix being analyzed as possible. A matrix spike sample is used to determine the effects of matrix interferences on analytical accuracy of a sample. A laboratory control sample is an analyte-free matrix spike with known concentration of target analytes that is used to measure the analytical accuracy and determine laboratory precisions. This definition provides clarity for the testing laboratories.

Proposed subsection (oo) defines “method blank” as an analyte-free matrix to which reagents are added in the same volumes or proportions as are used in sample preparation and that is processed in exactly the same manner as the samples. A method blank is used to control for potential laboratory-introduced contamination and to ensure laboratory contamination does not result in false-positive results. Preparation of a method blank sample is a necessary component of quality control procedures, and providing the definition lends clarity to the regulations.

Proposed subsection (pp) defines “moisture content” as the percentage of water in a dry sample, by weight. Moisture content testing is one of the analysis a laboratory must perform on cannabis for regulatory compliance testing. This definition is necessary to clarify what is being measured when this test is performed.

Proposed subsection (qq) defines “non-target organism” as an organism that the test method or analytical procedure is not testing for and can be used in evaluating the specificity of a test method. This definition is necessary because non-target organisms are used in evaluating the specificity of a test method.

Proposed subsection (rr) defines “percent recovery” as the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate. A laboratory shall calculate the percent recovery by dividing the sample result by the expected result then multiplying that the quotient by 100. Percent recovery allows for determination of how much of the original substance (added at the beginning of an experiment) one ends up with or gets back at the end of the experiment. It is necessary to determine the validity of a test method or a particular matrix effect on the spiked analyte. This definition is necessary to provide clarity to regulated community and provides a standard calculation the laboratories will all use.

Proposed subsection (ss) defines “practical experience” as experience performing scientific analytical tests in a laboratory setting using equipment, instruments, kits, and materials

routinely found in a laboratory. Practical experience includes experience in any type of laboratory setting and is not limited to cannabis specific laboratories. This definition is necessary to explain what kind of experience is required for a person to hold certain positions in a licensed laboratory.

Proposed subsection (tt) defines “proficiency test” as an evaluation of a laboratory’s performance against pre-established criteria by means of interlaboratory comparisons of test measurements. Proficiency testing is a necessary component of ISO/IEC 17025 accreditation and is a means to regulate laboratories. This term is commonly used in the industry and is provided here for clarity.

Proposed subsection (uu) defines “proficiency test sample” as a sample that is prepared by a party, independent of the ISO/IEC 17043 accredited testing laboratory that is participating in a proficiency test, such that the sample has a concentration and identity of an analyte known to the party, but unknown to the testing laboratory and its employees. This definition is necessary to distinguish a proficiency test sample from other samples handled by the laboratory. A proficiency test sample is used to conduct proficiency testing, and the results of that test are used by ISO and by the Bureau to evaluate whether a laboratory is competent to test cannabis goods.

Proposed subsection (vv) defines “quality control” as a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels. “Quality control” is a term commonly used in the laboratory industry and this definition provides clarity for the regulations.

Proposed subsection (ww) defines “quality control sample” as a sample that is produced and used by a laboratory to assure the quality of the data and results. Quality control samples include blank samples, matrix spike samples, laboratory control samples, duplicate samples, and reference material samples. This broad definition is necessary to simplify the regulatory language.

Proposed subsection (xx) defines “reagent” as a compound or mixture added to a system to cause a chemical reaction or test if a reaction occurs. A reagent may be used to determine whether a specific chemical substance is present by causing a reaction to occur with the chemical substance. This definition is necessary to identify the substances used in the analytical process and is a common term.

Proposed subsection (yy) defines “reference material” as a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process. Reference material is a necessary component of a laboratory’s quality control procedures required to ensure confidence in test results.

Proposed subsection (zz) defines “reference method” as a method by which the performance of an alternate method is measured or evaluated. A reference method is necessary for method validation studies. Method validation studies must include comparison to a recognized reference method to demonstrate equivalence or increased performance, the significance of which must be determined statistically.

Proposed subsection (aaa) defines “relative percent difference” (RPD) as a comparative statistic used to calculate precision or random error. RPD must be calculated using the following equation:

$$\text{RPD} = (\text{representative sample measurement} - \text{duplicate-sample measurement}) / ([\text{representative sample measurement} + \text{duplicate-sample measurement}] / 2) \times 100\%$$

Relative percent difference is used to compare the amounts of an analyte present in two different samples. This definition is necessary because RPD is an important statistical tool used to ascertain precision or random error of measurement between two samples. This definition clarifies the meaning when the term is used in the regulations.

Proposed subsection (bbb) defines “relative standard deviation” (RSD) as the standard deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100. RSD must be calculated using the following equation. If any results are less than the limit of quantitation, the absolute value of the limit of quantitation is used in the following equation:

$$\text{RSD} = (s / x) \times 100\%; \text{ where } s = \text{standard deviation and } x = \text{mean recovery}$$

Relative standard deviation is used to determine how precise experimental data are. The more precise the data is, the smaller the RSD. This definition clarifies the meaning when the term is used in the regulations.

Proposed subsection (ccc) defines “representative” as a portion of a batch whose characteristics represent, as accurately as possible, the characteristics of the entire batch, thus allowing the results to be generalized. This definition is necessary because it provides clarity to the regulated community.

Proposed subsection (ddd) defines “representative sample” as a sample comprised of several increments of cannabis goods that are collected from a batch for testing. This definition is necessary to provide the regulated community with clarity.

Proposed subsection (eee) defines “requester” as the person who submits a request to the laboratory for testing of cannabis goods from an entity licensed under this division. The requester may be a licensed cultivator, licensed manufacturer, or licensed distributor. It is important to clearly define who the requester is for proper test analysis reporting and recordkeeping.

Proposed subsection (fff) defines “reserve sample” as any portion of a representative sample that was not used in the testing process. This definition is necessary to provide clarity to the regulated community.

Proposed subsection (ggg) defines “sample” as a representative part of, or a single item from, a batch which is comprised of several sample increments. This definition is necessary because the term “sample” is used in the context of laboratory testing and within these regulations.

Proposed subsection (hhh) defines “sample increment” as a portion of a batch that, together with other increments, makes up the sample. This definition is necessary to ensure the sampler will collect a number of increments, which, combined, will be the representative sample for that batch.

Proposed subsection (iii) defines “sampler” as the laboratory employee responsible for obtaining samples of cannabis or cannabis product from a distributor. The definition of “sampler” is necessary to clearly define the type of personnel in charge of collecting samples of cannabis and cannabis goods for testing.

Proposed subsection (jjj) defines “sanitize” as to sterilize, disinfect, or make hygienic. This definition is necessary to provide clarity on how clean the sampling area or working area in a laboratory needs to be. Proper sanitization of the sampling areas is required to minimize sample contamination.

Proposed subsection (kkk) defines “scope of accreditation” as the tests or types of tests performed, materials or products tested, and the methods used for testing cannabis or cannabis products for which the accreditation has been granted. This definition is necessary to ensure that testing laboratories are meeting the ISO/IEC 17025 requirements for accreditation.

Proposed subsection (lll) defines “standard operating procedure” (SOP) as a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action. This definition is provided because standard operation procedures are necessary for the laboratory to achieve efficiency and uniformity of performance while also reducing misunderstandings and failures to comply to with laboratory practices.

Proposed subsection (mmm) defines “tamper-evident” as a one-time-use security tape or seal that is affixed to the opening of a package, allowing a person to recognize whether the package has been opened. The “tamper evident” definition is necessary to clearly define the minimum way in which one may pack something that allows for detection of any interference with the package.

Proposed subsection (nnn) defines “target organism” as an organism that is being tested for in an analytical procedure or test method. This definition is necessary to specify the identity of organisms that the analytical test is targeting in a potential pool of other contaminating organisms. Target organisms are used in the context of microbial method validation requirements to determine the sensitivity and specificity of the method for a particular microbial pathogen.

Proposed subsection (ooo) defines “THC” and “delta-9 THC” as tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3. This definition is needed to identify the unique numerical identifier and name of this cannabinoid, as known in the scientific community, for which chemical testing may be required. This cannabinoid is the principal psychoactive constituent of cannabis.

Proposed subsection (ppp) defines “THCA” as tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0. This definition is necessary to identify the unique numerical identifier and name of this cannabinoid, as known in the scientific community, for which chemical testing may be required. THCA is a non-psychoactive cannabinoid found in raw and live cannabis. As cannabis dries, THCA converts to THC. Heat expedites this conversion in a process known as decarboxylation, which happens, for instance, when cannabis goods are smoked or vaporized.

Proposed subsection (qqq) defines “validation” as the confirmation by examination and objective evidence that the requirements for a specific intended use or analytical method are fulfilled. Validation is necessary to determine whether a particular test method or analytical equipment is fit for its intended use.

Proposed subsection (rrr) defines “water activity” as a measure of the quantity of water in a product that is available and therefore capable of supporting bacteria, yeasts, and mold. Water activity is reported in the unit A^w. This term is used in the regulations thus the definition provides clarity to the regulated community.

§ 5701. General Laboratory License Requirements

This proposed section would specify the test methods for which the laboratory must acquire ISO/IEC 17025 accreditation. This section is necessary to ensure that the laboratory meets the minimum standard of competency when performing each test method.

Proposed subsection (a) requires the laboratory to obtain and maintain ISO/IEC 17025 accreditation. This is a requirement under Business and Professions Code section 26100(g). ISO/IEC 17025 is an international standard that sets forth the general requirements for the competence of testing and calibration laboratories. It covers every aspect of laboratory management, from sample preparation to analytical testing proficiency, record keeping, and reports. It includes reviews of document control, corrective and preventive action, accommodation and environmental conditions, equipment, measurement uncertainty,

evidence of traceability, and sampling, and authorizing that laboratory's testing and calibration results are technically valid. ISO/IEC 17025 accreditation demonstrates that a testing and calibration laboratories operates a quality system, is technically competent, and can generate technically valid results.

This subsection goes on to specify the test methods for which a licensee must acquire such accreditation which include testing for cannabinoids, heavy metals, microbial impurities, mycotoxins, residual pesticides, residual solvents and processing chemicals, and if tested, terpenoids. Specifying the test methods for which the laboratories need ISO/IEC 17025 accreditation is necessary to ensure compliance with statute.

Proposed subsection (b) requires the laboratory to obtain ISO/IEC 17025 accreditation for each premises at which the laboratory conducts testing of cannabis good samples. This section is necessary to ensure that all cannabis laboratory analysis is performed with the same degree of competence which is verified through ISO/IEC 17025 accreditation, regardless of the premises location.

Proposed subsection (c) requires the laboratory to make available to the Bureau, upon request, all records associated with the laboratory's ISO/IEC 17025 certificate of accreditation. This section is necessary for the Bureau to evaluate whether the laboratory is technically competent and can generate technically valid results. Records associated with the laboratory's ISO/IEC 17025 accreditation is evidence of the laboratory's competence to carry out the testing required under this chapter. Competency to carry out these analytical tests is fundamental to producing reliable, accurate test results related to cannabis goods and is fundamental to the protection of public health.

§ 5702. Laboratory License Application

The proposed section specifies what information must be provided by the applicant in the application for a laboratory license. In addition to the general application requirements in section 5002, a laboratory license application requires information that is not required for other types of license applications.

Proposed subsection (a) requires the applicant to provide a valid ISO/IEC 17025 certificate of accreditation issued by a recognized accreditation body that attests to the laboratory's competence to perform testing, including all the required analytes for cannabinoids; heavy metals; microbial impurities; mycotoxins; residual pesticides; residual solvents and processing chemicals; and if tested, terpenoids. Accreditation is the formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to international standards. ISO/IEC 17025 is the general requirements for the competence of testing and calibration laboratories and is the most recognized ISO standard used by testing and calibration laboratories. ISO/IEC 17025 is the standard for which most labs must hold accreditation to be deemed technically competent. It is necessary to include that the laboratories must receive their accreditation the test methods

and all applicable analytes to provide clarity to the regulated community. The laboratories must prove proficient in the test methods and all the analytes. For example, a laboratory must be accredited for their pesticide analysis method, including all 66 pesticides described in this chapter. The integrity of analytical test results related to cannabis goods is very important as the patient/consumer will rely on the truthfulness of the test results. If analytical test results are altered or skewed, this may pose a significant public health safety risk.

Proposed subsection (b) requires the applicant to provide standard operating procedures for testing of cannabinoids; heavy metals; microbial impurities; mycotoxins; moisture content and water activity; residual pesticides; residual solvents and processing chemicals; and if tested, terpenoids. These SOPs are necessary for Bureau technical staff to review and ensure that each licensee is conducting testing in a manner consistent with these regulations and for the benefit of public health and safety.

Proposed subsection (c) requires the applicant to provide a method validation report testing of cannabinoids; heavy metals; microbial impurities; mycotoxins; foreign materials; moisture content and water activity; residual pesticides; residual solvents and processing chemicals; and if tested, terpenoids. This section is necessary to the Bureau's evaluation of an applicant's methods and to ensure that the methods are accurate, precise and rugged. In lieu of standardized methods for testing cannabis goods, which are not yet available, the Bureau has determined that method validation reports are a credible and essential element to determining whether an applicant can operate a laboratory in compliance with these regulations.

Proposed subsection (d) requires the applicant to provide standard operating procedures for the sampling of cannabis goods. A sampling SOP is a written document that provides detailed instructions for the performance of all aspects of sampling cannabis goods. Documented, consistent procedures for sampling are fundamental to a laboratory's ability to produce accurate, reliable testing results. Sampling errors can have a devastating effect on data relevancy and validity. Because a variety of cannabis goods exist, a sampling SOP is needed to ensure that the sampler is adequately prepared to obtain a representative sample from any type of cannabis goods batch and equally capable of maintaining the sample integrity until the sample is received at the analytical laboratory. A representative sample is one that was taken using procedures that ensure the sample proportionally reflects the different properties of the batch.

§ 5703. Provisional Testing Laboratory License

Section 5703 specifies that a cannabis testing laboratory may apply for a provisional license prior to receiving ISO/IEC 17025 accreditation status, provided that the laboratory meets all other requirements for licensure. It also specifies that a testing laboratory licensee shall pay fees for the provisional license and renew the provisional license, if needed. This

is necessary to allow testing laboratories that are in the process of obtaining ISO/IEC 17025 accreditation to acquire a state cannabis license and to inform them of their responsibilities related to the provisional license.

Proposed subsection (a) specifies that a testing laboratory may apply for a provisional license prior to receiving ISO/IEC 17025 accreditation if that laboratory meets all other licensure requirements and submits an application to the Bureau with an attestation that the laboratory is seeking or will seek ISO/IEC 17025 accreditation for all required testing methods. This provision is necessary to inform the Bureau that the testing laboratory does not yet have ISO/IEC 17025 accreditation, but intends to acquire a provisional cannabis testing laboratory license.

Proposed subsection (b) specifies that a provisional testing laboratory license is valid for 12 months after the issuance date. It also specifies the annual license fee for a provisional license shall follow the Bureau-proposed fee for a non-provisional license. This is necessary to establish the fees needed to obtain a provisional license and the provisional license's timeframe of validity.

Proposed subsection (c) specifies the actions, documents, and fees required to renew a provisional license along with the timeframe and deadline for submitting the required information to renew a provisional license. It also specifies that the Bureau is not responsible for providing a renewal notice to the testing laboratory holding a provisional license. This is necessary to establish the appropriate renewal deadlines and actions that are a testing laboratory licensee must follow while also clarifying the licensee's responsibility in the renewal process.

Proposed subsection (d) requires that the testing laboratory must not test any cannabis or cannabis products if the provisional license is not renewed prior to the expiration date. This is necessary to establish restrictions for a testing laboratory that holds an expired provisional license.

Proposed subsection (e) specifies that a license renewal form may be submitted up to thirty days after a provisional license has expired and that any licensees who submit late renewal forms will be subjected to a late fee. This is necessary to inform a testing laboratory licensee that a late renewal form will be accepted by the Bureau and to detail the repercussions for submitting a late renewal form.

Proposed subsection (f) enumerates the required information that the renewal application must contain. This is necessary to inform the testing laboratory licensee what information is required when they are seeking to renew a provisional license.

Proposed subsection (f)(1) specifies that the renewal application must contain the name of the licensee. It also specifies that the first and last name shall be provided if the licensee is an individual or the legal business name if the licensee is a business entity. This is necessary to ensure the Bureau has an identifying name for the licensee on the renewal form and to document that the license has not been transferred between issuance and renewal.

Proposed subsection (f)(2) specifies that the renewal application must contain the license number that the licensee holds, along with the license expiration date. This is necessary to

allow the Bureau to verify that the licensee has the appropriate license number and that the license has not expired prior to renewal.

Proposed subsection (f)(3) specifies that the renewal application must contain both the address of record for the licensee and the premises address. This is necessary to ensure the Bureau has the appropriate addresses for the licensee and to verify that the addresses have not changed between license issuance and renewal.

Proposed subsection (f)(4) specifies that the renewal application must contain an attestation from the licensee that the information provided to the Bureau is accurate and current. This is necessary to ensure the licensee is providing correct, up-to-date information to the Bureau and to hold the licensee responsible if incorrect information is submitted.

Proposed subsection (g) specifies that a provisional license may be renewed for twelve months. This is necessary to inform testing laboratories the timeframe of validity that a renewed provisional license has.

Proposed subsection (h) specifies that a provisional license may be renewed if the testing laboratory has applied for ISO/IEC 17025 accreditation. The testing laboratory must submit all the information and documentation required for a license renewal application along with an attestation that the laboratory's application for ISO/IEC 17025 of all testing methods is pending with the accrediting body. The testing laboratory licensee must provide the name of the accrediting body and the date the application was submitted to the accrediting body. This is necessary to allow the Bureau to verify and track the progress of the licensee's ISO/IEC 17025 accreditation.

Proposed subsection (i) specifies that the testing laboratory will notify the Bureau of the outcome for each ISO/IEC 17025 accreditation application within five business days of receipt from the accrediting body. It also specifies that the accrediting body's decision to grant or deny ISO/IEC 17025 accreditation status may allow the Bureau to terminate any provisional license the testing laboratory holds. This is necessary to establish the timeframe that the testing laboratory has to inform the Bureau of any ISO/IEC 17025 accreditation status updates as well as inform the testing laboratory that the Bureau has the authority to terminate the provisional license upon these updates.

Proposed subsection (j) specifies that the Bureau has the authority to revoke a provisional license at any time. This is necessary to inform the testing laboratory licensee that ownership of a provisional license is not definite.

§ 5704. Sampling Standard Operating Procedures

The proposed section specifies what information must be included in the laboratory's sampling standard operating procedures. This section is necessary to ensure that the laboratory submits standard operating procedures that are clear, detailed, and which use step-by-step instructions to help employees carry out routine operations. This is necessary to achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations.

Proposed subsection (a) requires the laboratory to develop and implement a sampling standard operating procedure using Form BCC-LIC-021.

The proposed Sampling – Standard Operating Procedures form identifies certain sampling information that applicants must provide in support of an application for testing laboratory licensure. Specifically, the form requires testing laboratory applicants to: (1) provide a description of the procedures used for obtaining representative samples; (2) provide a description of the procedures to obtain homogeneity samples for edible cannabis products; (3) specify equipment and supply used during sampling; (4) specify sampling tools; (5) specify any preventative measures used to avoid contamination; (6) specify the procedure for changing disposable gloves between each batch; (7) specify the procedure for weighing samples during collection; (8) specify the storage and preservation of samples; (9) specify the procedure for assigning each sample a unique identifier; (10) specify the procedure for recording the conditions during sampling and transportation on the chain of custody form; and (11) specify how the sampling procedure follows chain of custody protocols. The Sampling – Standard Operating Procedures form also requires a supervisory or management laboratory employee to sign-off on the Sample Preparation – Standard Operating Procedures.

The purpose of this form is to specify what information must be provided by the testing laboratory applicant with regards to how it will collect samples for state mandated testing. Documented, consistent procedures for sampling is fundamental to a laboratory's ability to produce accurate, reliable testing results. Sampling errors can have a devastating effect on data relevancy and validity. Because a variety of cannabis goods exist, a Sampling - Standard Operating Procedure form is needed to ensure that laboratories and their employees are adequately prepared to obtain a representative sample from and type of cannabis goods batch, and equally capable of maintaining the sample integrity until the sample is received at the analytical laboratory. The form provides the Bureau a mechanism to collect information that is necessary for the Bureau to evaluate whether applicants can comply with the laboratory sampling requirements for sampling. This form will also reduce potential misunderstandings regarding the relevant sampling preparation information that licensees must disclose to the Bureau for review.

Proposed subsection (b) requires the laboratory to retain a copy of the sampling SOP on the laboratory premises and ensure that the sampling SOP is accessible to the sampler during sampling. This is necessary to ensure that sampling is conducted in an appropriate manner while providing documented steps in case any future problems arise during the sampling process.

§ 5705. General Sampling Requirements

This proposed section provides the requirements for the collection and transport of all cannabis good samples. Sampling is the first step of the testing process for the laboratory and is an important aspect of obtaining valid test results. This section is necessary to ensure that the integrity of the sample is not compromised, and that the subsequently-produced testing data is accurate and reliable. This section is integral to quality assurance because it would provide a degree of standardization in the sampling process.

Proposed subsection (a) clarifies that the laboratory that obtains a representative sample from a distributor or microbusiness premises shall also be the laboratory to perform all the

required testing and at one licensed laboratory premises. This is necessary to ensure that the chain of custody requirements are met and that the sample integrity is not compromised. This is also necessary to provide clarity to the regulated public.

Proposed subsection (b) requires the sampler to obtain samples only cannabis good samples in final form. This is a requirement under Business and Professions Code section 26100 (b). This is also necessary to ensure that the testing results of the cannabis good sample accurately reflect the cannabis goods batch from which the sample was obtained and that the sample accurately reflects the product being sold to customers.

Proposed subsection (c) requires the sampler to collect a representative sample following the procedures specified in the laboratory's sampling standard operating procedure(s). This is necessary to ensure appropriate and approved sampling methods are followed by samplers of the licensed testing laboratory.

Proposed subsection (d) requires the sampler to obtain a representative sample from each cannabis goods batch. This provision is necessary to ensure that the sampler obtains a sample of the batch that accurately reflects the overall characteristics of the batch. This is a requirement under Business and Professions Code section 26110(d).

Proposed subsection (e) requires the laboratory to ensure that the sample obtained from a licensed distributor is transported and stored in a manner that prevents degradation, contamination, commingling, and tampering. This subsection also specifies that the testing laboratory is required to store the sample in a manner as indicated on the label, if applicable. This is necessary to clarify that it is the laboratory's responsibility alone to ensure that the sample is appropriately transported and stored in a way that will uphold the integrity of the sample and assure the reliability of the test results.

Proposed subsection (f) specifies that the sampler and the testing laboratory are responsible to complete a chain of custody (COC) form each sample collected and analyzed. This is necessary because the COC form is evidence that the sample integrity has been maintained and allows for proper traceability of the samples.

§ 5706. Chain of Custody (COC)

Proposed section 5706 requires the laboratory to establish standard operating procedures that provide for adequate chain of custody controls for samples transferred to the testing laboratory for testing. This is a requirement under Business and Professions Code section 26102(c). The proposed section specifies the components of an adequate chain of custody (COC) controls.

Proposed subsection (a) requires the laboratory to develop and implement a COC protocol that addresses sample transportation, handling, storage, and destruction. This is necessary to ensure that the laboratory follows a standard procedure to track and document the movement of the sample while it is in the laboratory's control. The accurate documentation of the sample transport, handling, storage, and destruction is necessary to the Bureau's ability to determine the reliability to the testing result¹. This requirement is also necessary

¹Taschwer M., et al., Determination of the Relative Percentage Distribution of THCA and THC in Herbal

for the laboratory to demonstrate compliance with the sample handling and storage requirements of this chapter.

Proposed subsection (b) requires the laboratory to use a COC form in its COC protocol and specifies the information that the sampler must record on the COC form. This is necessary to preserve the process and integrity of the sampling and testing processes which are integral to quality assurance. These provisions, which also in part specify the roles and responsibilities of the licensees, are necessary to provide accountability for proper sampling and testing which ensures that cannabis goods are safe for consumption by the public.

Proposed subsection (b)(1) requires the sampler to record, on the COC form, the laboratory's name, physical address, and license number. This is necessary to allow the Bureau and all licensees that handle cannabis good samples to identify the laboratory responsible for sampling and analyses of the samples and to document the laboratory's valid license or, to determine whether the entity does not hold a valid license.

Proposed subsection (b)(2) requires the sampler to record, on the COC form, the time and date that the sampling started and ended. This is necessary to document the date and time when the sampler took custody or possession of the sample. This information allows the Bureau to identify the date and point in time of potential problems related to the sampling or other activities occurring at the distributor premises.

Proposed subsection (b)(3) requires the sampler to record, on the COC form, the distributor or microbusiness licensee's name, address, and license number. This provision is necessary to identify the distributor and location from where the cannabis sample was obtained and to document the distributor's valid license or, to determine whether the entity does not hold a valid license.

Proposed subsection (b)(4) requires the sampler to record, on the COC form, the cultivator's, manufacturer's, or microbusiness' name, address, and license number. This provision is necessary to identify the producer of the batch from which the sample is obtained and to document the cultivator's manufacturer's, or microbusiness' valid license or, to determine whether the entity does not hold a valid license.

Proposed subsection (b)(5) requires the sampler to record, on the COC form, the batch number from which the sample was obtained along with the sample's unique sample identifier. This provision is necessary to ensure that the batch number is properly correlated with the sample obtained from the batch. Documentation of the unique sample identifier on the COC will ensure that each sample and corresponding batch number are distinguishable from others and will ensure that the correct sample and batch are paired with the correct COC form. The ability to distinguish samples and trace back to batches will enable the Bureau to efficiently and quickly halt the distribution of cannabis good batches that do not pass the requisite laboratory testing.

Proposed subsection (b)(6) requires the sampler to record, on the COC form, the matrix type being sampled, such as dried flower, concentrate, resin, etc. This information is necessary to identify the composition of the samples and to aid the laboratory in determining the requisite laboratory testing for each sample upon receipt at the laboratory. This subsection is also necessary to ensure that the laboratory is performing the appropriate tests based on the matrix type.

Proposed subsection (b)(7) requires the sampler to record, on the COC form, the total batch size by weight, by volume, or by unit count. This provision is necessary to ensure that the correct amount, whether by weight or by count, of sample is obtained relative to the entire size of the batch being sampled.

Proposed subsection (b)(8) requires the sampler to record, on the COC form, the weight or unit count of the representative sample collected. This provision is necessary to accurately trace the sample quantity collected and subsequently accepted at the laboratory. The ability to trace sample quantity allows the Bureau to verify that the correct amount is being collected for analyses and to monitor the remaining amount in the corresponding batch.

Proposed subsection (b)(9) requires the sampler to record, on the COC form, the sampling conditions or problems encountered during the sampling process, if any. This is necessary to document any unusual sampling circumstances that could potentially adversely affect subsequent testing results.

Proposed subsection (b)(10) requires the sampler to record, on the COC form, the printed and signed name of the distributor or microbusiness employee. This provision necessary to identify the distributor and will enable the Bureau to identify affected parties in the event or incident of alleged noncompliance, sampling errors, contamination, or similar issues.

Proposed subsection (b)(11) requires the sampler to record, on the COC form, the printed and signed name of the sampler. This provision is necessary to identify the person(s) responsible for sampling and will enable the Bureau to identify the affected parties responsible in the event or incident of alleged noncompliance, sampling errors, contamination, or similar issues.

Proposed subsection (c) requires the COC form document each time the sample changes custody between licensees, is transported, or is destroyed along with the date, time, and signatures of the persons involved in these activities. This is necessary to allow the Bureau to track the history of the sample and identify the parties responsible if any issues or events of noncompliance in the handling of cannabis samples are investigated.

§ 5707. Harvest Batch Sampling

Proposed section 5707 provides the requirements for sampling a harvest batch. A harvest batch may be sampled either as a prepacked or unpacked batch. This section describes how the licensed testing laboratories will obtain a representative sample from the harvest batch.

Proposed subsection (a) requires the sampler to obtain a representative sample from each prepacked or unpacked harvest batch. This subsection also specifies the representative sample must weigh 0.35% of the total harvest batch weight. This subsection is necessary to ensure that the sample is an accurate representation of the entire batch. There are several

factors that must be considered when determining the appropriate sample size by weight and increments needed, including the risk levels associated with the product, costs associated with producing the product, and costs associated with inspection, measuring, and testing.

The Bureau has determined that a minimum of 0.35% of the total harvest batch weight is needed to represent the characteristics of the entire batch and that the collection of 0.35% will result in reliable, statistically sound, analytical test results.

Proposed subsection (b) specifies that the sampler may collect greater than 0.35% of a prepacked or unpacked harvest batch if necessary to perform the required testing or to ensure that the samples obtained are representative. This is necessary to ensure that the laboratory obtains a sufficient sample for the tests to produce valid results.

Proposed subsection (c) prohibits the sampler from collecting samples from a prepacked or unpacked harvest batch that weighs greater than 50.0 pounds. This provision is necessary to clarify the maximum size of a prepacked or unpacked harvest batch from which a sampler may obtain samples. The Bureau has determined that the requirement that the sample be representative combined with the proposed minimum sample size based on batch size will together ensure a high level of confidence that the testing results accurately reflect the overall composition of contaminants, cannabinoids, and, if tested terpenes, present in the batch. This subsection further specifies that laboratory analyses of a sample collected from a harvest batch weighing more than 50.0 pounds shall be deemed invalid and the harvest batch from which the sample was obtained may not be released for retail sale. This provision is necessary to ensure consistency in sampling procedures.

Proposed subsection (d) enumerates the steps that the sampler must take when obtaining a representative sample from an unpacked harvest batch. This is necessary to ensure the sample obtained from an unpacked harvest batch is representative and that the sampling methods remain consistent with each sampled batch.

Proposed subsections (d)(1) specifies that the sampler must obtain a representative sample from an unpacked harvest batch by collecting the number of increments relative to the unpacked harvest batch size as listed in the table. This is necessary to ensure the sample size is 0.35% of the entire batch such that the sample quantity is sufficient to allow the laboratory to properly perform all required.² The Bureau has determined that the requisite sample size required to be obtained from a harvest batch will not result in undue loss of cannabis for testing. The Bureau is recommending the minimum size sample necessary to perform testing and necessary to constitute a representative sample of the entire batch.

Proposed subsections (d)(2) requires the sampler to obtain increments from random and varying locations of the unpacked harvest batch, both vertically and horizontally. This is necessary to ensure that random sampling is performed. This is also necessary to ensure the sample collected is representative of the entire batch by ensuring that increments are drawn from varying areas throughout the batch. To ensure random sampling is performed, one must collect many increments throughout the batch. This is necessary to ensure that the

² Interstate Technology Regulatory Council, *Incremental Sampling Methodology: Representative Sampling, Confident Decisions* <<http://www.itrcweb.org/ism-1/>> (as of Jun. 7, 2018).

batch is randomly sampled because random sampling will eliminate systematic bias, thus ensuring the representativeness of the sample collected. The harvest batch size and the minimum required number of increments to be obtained during sampling requires that the sampler obtain about 2 grams of sample per increment. Environmental sampling sometimes requires more increments than described in this section,³ but it was determined that 2 grams per increment would be a reasonable amount of sample to collect, considering the value of this specific commodity. Incremental sampling coupled with a total minimum amount of sample collected will ensure a representative sample of the batch is collected. For example:

From a harvest batch weighing 10 pounds, a sampler must obtain 8 increments totaling ~16 grams – each increment would weigh ~2.0 grams.

From a harvest batch weighing 20 pounds, a sampler must obtain 16 increments totaling ~32 grams – each increment would weigh ~2.0 grams.

From a harvest batch weighing 30 pounds, a sampler must obtain 23 increments totaling ~48 grams – each increment would weigh ~2.1 grams.

From a harvest batch weighing 40 pounds, a sampler must obtain 29 increments totaling ~64 grams – each increment would weigh ~2.2 grams.

From a harvest batch weighing 50 pounds, a sampler must obtain 34 increments totaling ~80 grams – each increment would weigh ~2.3 grams.

Proposed subsections (d)(3) requires the sampler, to the extent possible, to obtain from an unpacked harvest batch that are of equal weight and number if the unpacked harvest batch is stored in multiple containers. This is necessary to ensure the sample is representative of the entire batch and not just one portion of the batch⁴. This is also necessary to ensure the sample collected is representative of the entire batch by ensuring all containers from throughout the batch are tested.

| Unpacked Harvest Batch Size (pounds) | Number of Increments (per sample) |
|---|--------------------------------------|
| ≤ 10.0 | 8 |
| 10.1 – 20.0 | 16 |
| 20.1 – 30.0 | 23 |
| 30.1 – 40.0 | 29 |
| 40.1 – 50.0 | 34 |

³ Interstate Technology Regulatory Council, *Incremental Sampling Methodology: Representative Sampling, Confident Decisions* <<http://www.itrcweb.org/ism-1/>> (as of Jun. 7, 2018).

⁴ Center for Drug Evaluation and Research (CDER), U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment (Oct. 2003) Pharmaceutical Current Good Manufacturing Practices (CGMP) <<https://www.fda.gov/ohrms/dockets/98fr/03d-0493-gdl0001.doc>> (as of Mar. 30, 2017).

§ 5708. Cannabis Product Batch and Pre-Roll Batch Sampling

Proposed section 5708 provides the requirements for sampling a cannabis product batch or nonmanufactured cannabis batch. A cannabis product batch or pre-roll batch is comprised of one or more units, each of which must be prepacked for retail sale prior to conducting sampling. This section describes how the laboratory must obtain a representative sample from the cannabis product batch or nonmanufactured cannabis batch.

Proposed subsection (a) requires the sampler to obtain a representative sample from each cannabis product batch or pre-roll batch being sampled. This subsection is necessary to ensure that the sample accurately represents the characteristics of the entire batch. In determining the appropriate sample size, the Bureau considered several factors including the specific tests that must be performed, the amount of sample needed for each test, the potential contaminants in the product, logistics of sampling, and costs.

Proposed subsection (b) specifies that the sampler may collect a greater number of increments if necessary to perform the required testing or to ensure that the samples obtained are representative. This subsection is necessary to ensure that the laboratory obtains a sufficient sample for the tests to produce valid results.

Proposed subsection (c) prohibits the sampler from collecting samples from a cannabis product batch that is greater than 150,000 units. This provision is necessary to clarify the maximum size of a cannabis product batch or pre-roll batch from which the sampler may obtain samples. Currently, cannabis products are produced and sold in various forms and sizes for both the medicinal and adult-use consumer markets. Due to the wide variety in product types, the Bureau has determined that the ISO 2859 tables are the most appropriate standard for determining the number of sample increments relative to a batch size⁵. The ISO 2859 tables are a United States standard with equivalents in all national and international standardization organization (ANSI/ASQC Z1.4, NF06-022, BS 6001, DIN 40080) that specifies an acceptance sampling system for inspection by attributes. The steps of batch size are modified and the maximum batch size is limited to 150,000 units. If a batch size is more than 150,000 units, it should be divided and resized to no more than 150,000 units for sampling.

Proposed subsection (d) requires the sampler to collect a minimum number of increments, as specified in the table, from each cannabis product batch or nonmanufactured cannabis batch relative to the batch size. The number of increments required to be collected per sample are based on the ISO 2859 tables, discussed above.⁶ This subsection further clarifies that each increment constitutes one packaged unit. This clarification is necessary given the wide variability in product types.

⁵ International Organization for Standardization (ISO), and International Electrotechnical Commission (IEC), *Standard ISO/IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories* (2nd ed. May 2005)

<http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf> (as of Jun. 7, 2018).

⁶ International Organization for Standardization (ISO) 2859-5, *Sampling Procedures for Inspection by Attributes, subsection 11.1:* <http://allaboutmetallurgy.com/wp/wp-content/uploads/2016/12/ISO-2859-Part-5.pdf> (as of Jun. 10, 2018).

| Cannabis Product and Nonmanufactured Cannabis Batch Size (units) | Number of Increments (per sample) |
|---|--------------------------------------|
| ≤ 50 | 2 |
| 51 – 150 | 3 |
| 151 – 500 | 5 |
| 501 – 1,200 | 8 |
| 1,201 – 3,200 | 13 |
| 3,201 – 10,000 | 20 |
| 10,001 – 35,000 | 32 |
| 35,001 – 150,000 | 50 |

§ 5709. Laboratory Transportation of Cannabis Good Samples

Proposed subsection (a) provides the requirements for the laboratory transport of cannabis good samples. This is necessary to establish security and safety requirements during the transportation of cannabis good samples.

Proposed subsection (a)(1) requires the licensee to transport cannabis good samples in a vehicle or trailer from which the cannabis good sample is not visible or identifiable from the outside of the vehicle or trailer. The proposed subsection also clarifies that for purposes of this section, inside of the vehicle includes the trunk. Requiring cannabis good samples to not be visible or identifiable during transport is necessary to reduce the risk of theft or robbery, which exposes the general public to harm and danger. This provision would prohibit the licensee from using air transport, watercraft or drones, which often involve compliance with federal laws and regulations and is unduly burdensome and outside the purview of the Bureau's current capabilities. This provision would also prohibit the licensee from using human powered and unmanned vehicles, which are less secure and more susceptible to third party interference and intrusion, are prohibited for safety of the public and security of the cannabis goods. These requirements on cannabis good sample transport are necessary to reduce the risk of loss or theft, and attempts to limit potential conflicts with federal law and regulation.

Proposed subsections (a)(2) - (a)(4) clarify the measures to be taken to ensure the security of cannabis good samples during transport and are necessary to clearly identify the methods needed to safely and securely transport cannabis good samples. These measures are

necessary to prevent diversion of cannabis good samples into the illegal and unregulated market. This section would prohibit the licensee from leaving a vehicle or trailer containing cannabis goods samples unattended in a residential area or parked overnight in a residential area; requirements necessary to discourage theft and protect public safety.

Proposed subsection (a)(5) requires the laboratory to ensure that any vehicle or trailer transporting cannabis good samples has a vehicle alarm system. This is necessary to help deter theft and unauthorized entrance into the vehicle. In the case a vehicle containing cannabis goods is burglarized, an alarm would help alert the licensee, employees, and enforcement personnel, and deter such criminal behavior.

Proposed subsection (a)(6) requires the laboratory to ensure that packages or containers holding cannabis good samples are neither tampered with nor opened during transport. This is necessary to ensure that samples are not comingled, contaminated, degraded, or otherwise compromised and product inaccurate and unreliable laboratory test reports. This is necessary because if there is evidence of improper sample handling, the laboratory cannot ensure the integrity of the sample. The integrity of the sample and ultimately the integrity of the sample results related to cannabis goods is very important as the patient/consumer will rely on the truthfulness of the test results. If analytical test results are altered or skewed, this may pose a significant public health safety risk.

Proposed subsection (a)(7) requires the laboratory transporting cannabis to travel only between licensees for whom the laboratory is conducting compliance testing or quality assurance testing and the laboratory's licensed premises when engaged in the transportation of cannabis goods. This is necessary to ensure that the samples will arrive at the intended destinations in the same quality and quantity as it was in before transport occurred. This is necessary to limit the risk of adulteration of cannabis good samples, and ensure protection of the public health and safety. It also reduces the likelihood of diversion into the illegal or unregulated market.

Proposed subsection (a)(8) allows the laboratory to transport multiple cannabis good samples obtained from multiple licensees at once. This is necessary to provide clarification to the regulated community and allow for efficient sample transportation.

Proposed subsection (a)(9) allows vehicles or trailers transporting cannabis good samples are subject to inspection by the Bureau at any licensed premises or during transport at any time. This is necessary for clarification and to make the licensee aware that vehicles used to transport cannabis good samples may be inspected by the Bureau at any licensed location, or during transport, to ensure the vehicle is properly equipped, carrying the required documentation, and contains a shipment compliant with the statute and regulations.

Proposed subsection (a)(10) prohibits persons under the age of 21 years from being in a vehicle or trailer transporting cannabis good samples . This is necessary for clarification and to make the licensee aware that no one under the age of 21 is permitted in the vehicle or trailer for any reason.

Proposed subsection (a)(11) prohibits any person other than an employee of the laboratory or security personnel from being in a vehicle that is transporting cannabis good samples. This is necessary for clarification purposes, as employees must be at least 21 years or older as required by proposed section 5031 of this division.

Proposed subsection (b) requires the licensee to provide, to the Bureau, information about the vehicle used to transport cannabis good samples including proof of ownership and proof of insurance for each vehicle or trailer used to transport cannabis or cannabis product samples. This is necessary to cross-reference the validity of the documentation provide during an inspection at any licensed location, or during transport, to ensure the vehicle is properly equipped, carrying the required documentation, and contains a shipment compliant with the statute and regulations.

Proposed subsection (c) and (d) requires the laboratory to provide the Bureau with the information required by this section in writing for any new vehicle or trailer that will be used to transport cannabis good samples prior to using the vehicle or trailer and provide any changes to the information in 30 days. It is important for the Bureau to have the most up to date information regarding a licensee's activities. However, the Bureau has determined that 30 days is an appropriate amount of time that allows the licensee a reasonable opportunity to provide the Bureau with notice. The Bureau will need this information to cross-reference the validity of the documentation provide during an inspection at any licensed location, or during transport, to ensure the vehicle is properly equipped, carrying the required documentation, and contains a shipment compliant with the statute and regulations.

§ 5710. Laboratory Receipt of Samples Obtained from a Distributor or Microbusiness

Proposed subsection (a) clarifies that the laboratory may accept and analyze a sample from a distributor or microbusiness for the required testing under this division only if there is an accompanying COC form for the sample. This is necessary and important to ensure the samples are being handled in a manner which will prohibit and prevent degradation or contamination. Recording this information ensures sample integrity, thus assuring the subsequent analytical test results.

Proposed subsection (b) requires the laboratory employee who receives the sample to date, print, and sign their name on the accompanying sample COC. This is necessary to identify and document the person responsible for receiving the sample at the laboratory's analytical site, prior to commencing testing. Identification of this person is necessary to track and identify potential sources of contamination or other interferences that may affect the test result.

Proposed subsection (c) prohibits the laboratory from analyzing a sample for certain scenarios, including when: (1) there is no COC form; (2) the tamper-evident material is broken; or (3) there is evidence of sample commingling, contamination, degradation, or a related occurrence rendering the sample unusable for analytical testing when the sample is received at the laboratory. This provision only applies to samples obtained from a distributor or microbusiness.

Proposed subsection (c)(1) prohibits the laboratory from analyzing a sample that is received at the laboratory without the requisite COC form. This is necessary because all sample collection information and sample movements are recorded on the COC to ensure the integrity of the sample and ultimately the integrity of the sample results. Furthermore, a COC form is required pursuant to Business and Professions Code 26102(k).

Proposed subsection (c)(2) prohibits the laboratory from analyzing a sample for which, upon receipt at the laboratory, the tamper-evident material is broken. This is necessary to ensure that the sample, as received, has remained properly sealed and protected from potential contamination from the point in time that the sample was received until the sample is received at the laboratory. Failure to maintain the tamper-evident material of a sample container will result in unverifiable data results.

Proposed subsection (c)(3) prohibits the laboratory from analyzing a sample if, upon receipt at the laboratory, there is evidence of sample commingling, contamination, degradation, or a related occurrence rendering the sample unusable for analytical testing when the sample is received at the laboratory. This is necessary to ensure that all samples received at the laboratory have been properly secured, packaged, and stored such that the testing of such samples will produce reliable data.

§ 5711. Laboratory Analyses Standard Operating Procedures

Proposed subsection (a) requires the laboratory to develop, implement, and maintain written standard operating procedures for sample preparation and test methods. This is necessary so that the Bureau may ensure that the laboratory is following procedures and practices consistent with ISO/IEC 17025 accreditation and the guidelines incorporated by reference, which include: US Food and Drug Administration's Bacterial Analytical Manual, 2016; AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC International, 20th Edition, 2016; and United States Pharmacopeia and the National Formulary's Methods of Analysis for Contaminant Testing, 2016.⁷ Business and Professions Code section requires the laboratory to conduct all testing required by MAUCRSA in a manner consistent with general requirements for the competence of testing and calibrations activities, including sampling and using verified methods. This proposed section clarifies the components of sample preparation and test method SOPs to ensure competency of laboratory analytical processes and compliance with the statute.

Proposed subsection (a)(1) requires the laboratory to use Form BCC-LIC-022 (Rev. 7/18) for their sample prep procedures. The proposed Sample Preparation – Standard Operating Procedures form identifies certain sample preparation information that applicants must provide in support of an application for testing laboratory licensure. Specifically, the form requires testing laboratory applicants to: (1) describe sample homogenization procedures used for all matrices tested; (2) provide a description of storage and handling procedures for samples; (3) specify preservation methods used for samples; and (4) provide the hold time for all sample types and matrices. The Sample Preparation – Standard Operating

⁷ United States Pharmacopeia - National Formulary, 2017. (USP 40 NF 35)
<<http://www.usp.org/products>>

Procedures form also requires a supervisory or management laboratory employee to sign-off on the Sample Preparation – Standard Operating Procedures.

The purpose of this form is to specify what information must be provided by the testing laboratory applicant with regards to how it will handle samples collected for state mandated testing. This form is necessary to standardize the sampling procedures developed and implemented by all testing laboratory licensees. This form is also necessary to ensure that licensed testing laboratories are sampling cannabis goods in the same manner, with the same minimum standards, thus making their results accurate and reliable. The form provides the Bureau a mechanism to collect information that is necessary for the Bureau to evaluate whether applicants adequately prepare samples for testing. This form will also reduce potential misunderstandings regarding the relevant sampling preparation information that licensees must disclose to the Bureau for review.

Proposed subsection (a)(2) also requires laboratories to use Form BCC-LIC-023 (Rev. 7/18) for their test method standard operating procedures. Proposed Form BCC-LIC-023 requires applicants to provide information regarding the analytes and matrices tested by the method; the extraction procedures used; descriptions of the instruments and equipment used; and the procedures for making reagents, solutions, standards, and reference materials. In addition, the proposed form requires the testing laboratory applicant to provide the method sensitivity; the types, frequencies, and acceptance criteria for quality control samples; the procedure for analyzing analytical batch samples; corrective action procedures used when LQC samples fail; any calculations used; and any potential interferences with the analysis. Lastly, the proposed form requires applicants to specify the ISO 17025 accreditation body and accreditation or certificate number for the method if applicable.

All the information requested in the proposed form would allow the Bureau to get a better understanding of the testing laboratory applicant's ability to properly engage in cannabis testing. This will allow the Bureau to better assess the likelihood that the applicant will comply with all requirements. This in turn, will allow the Bureau to be better able to determine whether the applicant is fit for licensure.

Proposed subsection (a)(3) requires the laboratory to retain a copy of each test method SOP on the laboratory premises and ensure that the sampling SOP is accessible to the sampler during sampling. This is necessary to ensure that the laboratory employees who perform test methods have consistent access to the test method SOPs that are required to be used. Accessibility to the test method SOPs is necessary to ensure consistent implementation of the complex, detailed steps of each test methods and of the corrective actions necessary when specific, complicated problems arise.

Proposed subsection (a)(4) requires the laboratory to make each SOP available for inspection by the Bureau upon request, as well as any other SOPs associated with the licensee's ISO/IEC 17025 certificate of accreditation. This section is necessary because it enables the Bureau to evaluate the laboratory's level of technically competency and to identify any inconsistencies or irregularities between the laboratory's ISO/IEC 17025 accreditation and the test method SOP. Consistency between the laboratory's accreditation records and the laboratory's test method SOPs is necessary to demonstrate the laboratory's

overall competence to carry out the testing required under this chapter. Competency to carry out these analytical tests is fundamental to producing reliable, accurate test results related to cannabis goods and is fundamental to the protection of public health. This is also necessary because it ensures records are available to the Bureau in the event that records need to be referenced because of a safety recall and/or the need to trace-back or trace-forward investigation records related to cannabis.

§ 5712. Test Methods

Business and Professions Code section 26100(f) requires the laboratory to conduct all testing required by MAUCRSA in a manner consistent with the general requirements for the competence of testing and calibrations activities, including sampling and using verified methods.

Proposed subsection (a) requires the laboratory to develop, implement, and validate test methods for the analyses of cannabis good samples. This is necessary to ensure compliance with Business and Professions Code section 26100(f) which requires, in part, the laboratory to use verified methods.

Proposed subsection (b) specifies the guidelines and scientific standards upon which the laboratory may rely to develop test methods. This is necessary because it provides a mechanism to assure that the testing of cannabis goods is standardized, by using available, verified methods, in lieu of specific methods for testing cannabis goods, which are not yet available.

Proposed subsection (b)(1)) requires the laboratory to develop, implement, and validate test methods for the analysis of microbial contaminants which, to the extent possible, align with the US Food and Drug Administration's (USFDA) Bacterial Analytical Manual, 2016. The USFDA's Bacteriological Analytical Manual (The BAM) is a collection of procedures preferred by analysts in USFDA laboratories for the detection of pathogens (bacterial, viral, parasitic, plus yeast and mold) and of microbial toxins in consumer goods.⁸ The BAM contains the USFDA's scientific standards for testing various contaminants and is used worldwide in laboratories to ensure that consumer products are safe. The Bureau has determined that the BAM methods are scientifically valid and provide the appropriate guidance for laboratories when developing methods for the detection of microbial contaminants.

Proposed subsection (b)(2) requires the laboratory to develop, implement, and validate test methods for the analysis of chemical contaminants which, to the extent possible, align with the AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC

⁸ U.S. Food and Drug Administration, *Bacteriological Analytical Manual (BAM)* <<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>> (as of Mar. 30, 2017).

International, 20th Edition, 2016.⁹ The AOAC is a non-profit scientific association that publishes standardized methods for the analysis of chemical contaminants in various matrices. The Bureau has determined that the AOAC methods are scientifically valid and provide the appropriate guidance for laboratories when developing methods for the detection of contaminants.

Proposed subsection (b)(3) requires the laboratory to develop, implement, and validate test methods for the analysis of contaminants which, to the extent possible align with monographs published by the United States Pharmacopeia (USP) Convention National Formulary (USP-NF). The USP publishes standards for medicines, food ingredients, dietary supplement products, and ingredients to ensure that these products are of the appropriate identity, as well as strength, quality, purity, and consistency. The Bureau has determined that the USP-NF methods are scientifically valid and provide the appropriate guidance for laboratories when developing methods for the detection of contaminants.

§ 5713. Validation of Test Methods

Proposed section 5713 specifies the requirements that the testing laboratory must adhere to for validation of non-standard, amplified, or modified test methods used in cannabis testing. Method validation is a process by which the laboratory confirms by examination, and provides objective evidence, that the requirements for specific uses of a test method are fulfilled. It serves to demonstrate that the method can detect and identify an analyte, or analytes, in one or more matrices to be analyzed, on one or more instruments or platforms, and with a demonstrated sensitivity, specificity, accuracy, reproducibility, robustness, and precision to ensure that the results are meaningful and appropriate to decide.¹⁰ There are currently no established standard methods for microbial or chemical testing of cannabis goods. It is necessary for the Bureau to set guidelines for method validation that the cannabis testing laboratories will need to perform on their test methods.

Proposed subsection (a) allows the laboratory to use a nonstandard, amplified, or modified test method to perform method validation. These types of methods are used to test for an analyte of interest, but are not adopted by the industry as the standard method. This section is necessary to clarify the acceptable methods testing laboratories may use to perform method validation, because there is not yet a standardized method analyzing cannabis good samples. This section is also necessary to specify the extent of validation that the laboratory is required to conduct for analyses of cannabis good samples.

⁹ AOAC International's *Official Methods of Analysis*, 20th Edition, 2016
<https://www.aoac.org/AOAC_Prod_Imis/AOAC_Member/PUBSCF/OMACF/OMAP_M.aspx?WebsiteKey=2e25ab5a-1f6d-4d78-a498-19b9763d11b4&hkey=5142c478-ab50-4856-8939-a7a491756f48&OMACCO=2#OMACCO>

¹⁰ FDA Foods and Veterinary Medicine Science and Research Steering Committee. Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition.

Proposed subsection (b) requires laboratories to follow the guidelines set forth in the 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, to validate test methods for the microbial analysis. This document is the FDA's microbial methods validation standard operating procedure and establishes the requirements that must be fulfilled in the evaluation of microbial methods used in the FDA's testing laboratories. Cannabis goods are novel in terms of sample matrices and the analytical methods used to detect microbial contamination. Method validation for analyzing each matrix type is necessary to ensure that the methods used are fit for their intended use. Validation of method performance with a new matrix is intended to assure that the new matrix will produce accurate and reliable results for all the analytes in the scope of the method.¹¹ The Bureau has determined that the FDA methods for microbial contaminant analysis are scientifically valid and provide the appropriate guidance for the laboratory when developing methods.

Proposed subsection (b)(1) requires the laboratory to include and address specific criteria when validating test methods for microbial analysis. The proposed subsection specifies the number of organisms needed for inclusivity (sensitivity) and exclusivity (specificity), the number of analyte levels per matrix (for both quantitative and qualitative methods), and the number of replicates per matrix at each level tested. These criteria are based off the FDA's guidelines for a level one validation study for microbial analyses.¹² This is necessary to ensure that the laboratory is technically competent and can generate technically valid results in the performance of method validation for microbial analysis based on standards used by the industry.

Proposed subsection (c) requires the laboratory to follow the guidelines set forth in the US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM*, 2nd Edition, 2015,¹³ to validate test methods for the chemical analysis. This document is the FDA's chemical methods validation standard operating procedure and establishes the requirements that must be fulfilled in the evaluation of chemical methods to be used in the FDA's testing laboratories. Cannabis goods are novel in terms of sample matrices and the analytical methods used to detect chemical contaminants. Method validation for analyzing each matrix type is necessary to ensure that the methods used are fit for their intended use. Validation of method performance with a new matrix is intended to assure that the new matrix will produce accurate and reliable results for all the analytes

¹¹ US Food and Drug Administration.

<https://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm>. Accessed April 17, 2018.

¹² US Food and Drug Administration.

<https://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm>. Accessed April 17, 2018.

¹³ US Food & Drug Administration Office of Foods and Veterinary Medicine, Guidelines for the Validation of Chemical Methods for the FDA FVM Program, April 2015.

<https://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM273418.pdf>. Accessed April 17, 2018.

in the scope of the method. This is necessary to ensure that the laboratory is technically competent and can generate technically valid results in the performance of method validation of chemical analysis.

Proposed subsection (c)(1)(A) requires the laboratory to address “accuracy” when validating test methods for chemical analyses of cannabis good samples. Accuracy can be defined as the closeness between a test result and an accepted reference value. This is necessary because it is important that the results for any testing reported by the testing lab to be reliable and reproducible.

Proposed subsection (c)(1)(B) requires the laboratory to address “precision” when validating test methods for chemical analyses of cannabis good samples. Precision can be defined as the closeness between independent test results obtained under specified conditions. This is necessary because for a method to be considered valid, the lab must be able to reproduce the accurate result consistently.

Proposed subsection (c)(1)(C) requires the laboratory to address “linearity and range” when validating test methods for chemical analyses of cannabis good samples. Linearity can be defined as the ability of a method, within a certain range, to provide an instrumental response or test results proportional to the quantity of analyte to be determined in the test sample. Range can be defined as the interval of concentration over which the method provides suitable accuracy and precision. This is necessary because samples that test outside of the linearity or range of calibration will not necessarily be accurate or precise. One way to bring these samples into the calibration curve is to dilute the extract, or re-prepare the sample using less mass/volume.

Proposed subsection (c)(1)(C)(i) specifies the acceptable coefficient of determination (r^2) for all calibration curves. Methods that are performed and validated on instruments should have an r^2 of 0.99 or greater. This is necessary to ensure accurate and reproducible data. An r^2 of 0.99 or better is a typical requirement in EPA and DoD methods as an indication of a “good” calibration curve.

Proposed subsection (c)(1)(C)(ii) specifies the LOQ for analytes tested shall be within the linear range of the calibration curve. This is necessary to ensure that the laboratory is accurately able to quantify the results reported.

Proposed subsection (c)(1)(D) requires the laboratory to address “calibration standard” when validating test methods for chemical analyses of cannabis good samples. Calibration standard can be defined as a known amount or concentration of analyte used to calibrate the measuring/detection. Proposed subsection (c)(1)(D)(i) requires the calibration curves have a minimum of five calibration standards. A calibration curve is a mathematical tool used in analytical chemistry that provides a set of reference points that unknown chemical substances can be compared to. The calibration curve is obtained by fitting an appropriate equation to a set of experimental data or calibration data, consisting of the measured responses to known concentrations of analyte. The minimum number of five calibration standards or five calibration points within the curve, was chosen because it was determined to be the minimum number that would be able to create a meaningful correlation between the points in the curve. If a meaningful correlation is not achieved, the calibration curve would be meaningless, thus the instrument and subsequent measured concentrations are

meaningless. Furthermore, this requirement is necessary because there are no standardized methods for cannabis analysis at this time, and requiring a minimum number of calibration standards to be used in the curve will help achieve equilibrium between the laboratories.

Proposed subsection (c)(1)(D)(ii) requires that each calibration curve must include an Initial Calibration Verification (ICV). An ICV is a standard that is prepared from a different source (vendor or different producer) than that of the calibration standards. Requiring that each calibration curve include an ICV is necessary to ensure the accuracy and precision of the calibration standards.

Proposed subsection (c)(1)(E) requires that the laboratory address “sensitivity and selectivity” when validating test methods for chemical analyses of cannabis good samples. Sensitivity can be defined as the gradient of the response curve or slope of the calibration curve at a level near the LOQ. Selectivity can be defined as the extent to which a method can determine particular analyte(s) in a mixture(s) or matrix(es) without interferences from other components of similar behavior. This is necessary because the selectivity determines the likelihood of having false positives for a particular analyte. The sensitivity of a method determines at what level a laboratory can confidently report an accurate value for an analyte in a particular matrix, using a specific method.

Proposed subsection (c)(1)(F) requires the laboratory to address the “Limit of detection and limit of quantitation” when validating test methods for chemical analyses of cannabis good samples. LOD can be defined as the minimum amount or concentration of analyte that can be reliably distinguished from zero. LOQ can be defined as the minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision. It is necessary to require laboratories to establish LODs and LOQs so the Bureau is able to know at what level a laboratory can confidently report an accurate value for an analyte in a particular matrix, using a specific method.

Proposed subsection (c)(1)(G) requires the laboratory to address “recovery” when validating test methods for chemical analyses of cannabis good samples. Recovery can be defined as the proportion of analyte (added) remaining at the point of the final determination from the analytical portion of the sample measure. This is necessary because recoveries are related to quality control and the accuracy and precision of the method.

Proposed subsection (c)(1)(H) requires the laboratory to address “reproducibility” when validating test methods for chemical analyses of cannabis good samples. Reproducibility can be defined as precision obtained under observation conditions where independent test results are obtained with the same method on identical test items in different test facilities with different operators using different equipment. This is necessary because reproducibility is one component of the precision of a measurement or test method.

Proposed subsection (c)(1)(I) requires the laboratory to address “robustness” when validating test methods for chemical analyses of cannabis good samples. Robustness can be defined as a measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage. This is necessary because the robustness of the method is related to the strength of the method and the ability toward reproducibility.

Proposed subsection (c)(2) requires the laboratory to use certified reference materials to validate testing methods for chemical of cannabis good samples. It also enumerates the different test methods for which the laboratory shall use the certified reference materials. The recovery of these certified reference materials must be between 80% and 120% for the method to be deemed valid. Certified reference materials are integral to determining analyte recoveries, matrix interferences, method accuracy, and precision in method validation. Certified reference material is characterized by metrology, or the science of weights and measures. Certified reference material is accompanied by a certificate that provides the value of the specified property, its associated uncertainty (typically very low), and a statement of metrological traceability. It is reasonable to expect that the laboratories can achieve a recovery of 80%-120% with such a precise traceable amount of concentration contained in the certified reference material. If a laboratory is unable to measure a certified reference material sample and obtain a result where the recovery is within the acceptance criteria, it would determine that the method is not optimized, and the laboratory would not be able to accurately measure the specific analyte in question. Furthermore, subsequent reported results for the analyte may not be accurate. The variance of 80%-120% is quite generous when considering the amount of concentration in the certified reference material is very precise, often times with a meniscal amount of uncertainty. This section is necessary because it enables the Bureau to ensure that the laboratory performs acceptable method validation.

Proposed subsections (c)(1) to (c)(7) specify the test methods for which the laboratory is required to use certified reference materials for method validation. This is necessary because it enables the Bureau to ensure that the laboratory has determined analyte recoveries, matrix interferences, method accuracy, and precision in their analysis methods.

Proposed subsection (d) requires the laboratory to generate a validation report for each test method. It also enumerates the required information that shall be incorporated in each validation report. This is necessary because it enables the Bureau to ensure that the laboratory performs accurate and adequate method validation for each test method performed.

Proposed subsection (d)(1) requires that each validation report contain any instrument calibration data. A calibration curve is a mathematical tool used in analytical chemistry that provides a set of reference points that unknown chemical substances can be compared to. This requirement is necessary because it enables the Bureau to ensure the accuracy of the test method.

Proposed subsection (d)(2) requires that each validation report contain raw data. Raw data can include, but is not limited to, analytical instrument printouts with analyte concentrations, sample preparation system printouts, handwritten calculations, and chromatograms. This requirement is necessary because it enables the Bureau to trace the integrity of the data and to hold laboratories accountable for testing, thus deterring testing laboratories from producing fictitious data in lieu of performing the actual analysis (also known as “dry-labbing”).

Proposed subsection (d)(3) requires that each validation report contain cannabis reference materials or certified reference material results. This is necessary because it enables the

Bureau to evaluate the quality of data produced by the laboratory and to validate analytical measurement methods, including the calibration of instrument.

Proposed subsection (d)(4) requires that each validation report contain any data and calculations pertaining to LOD and LOQ determinations. LOD can be defined as the minimum amount or concentration of analyte that can be reliably distinguished from zero. LOQ can be defined as the minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision. This is necessary because it enables the Bureau to determine the level at which the laboratory can confidently report an accurate value for an analyte in a particular matrix, using a specific method.

Proposed subsection (d)(5) requires that each validation report contain the laboratory quality control (LQC) report. The LQC sample report includes LQC acceptance criteria, measurements, analysis dates, and matrix types. This is necessary because it enables the Bureau to evaluate how the laboratory achieves accurate results while ensuring the data from the quality control samples are precise.

Proposed subsection (d)(6) requires that each validation report contain any worksheets, forms, pictures, or copies of laboratory notebook pages related to the method validation performed by the laboratory. This is necessary because it enables the Bureau to ensure the laboratory includes any pertinent documentation related to the verification process and to validate their verification data and results.

Proposed subsection (d)(7) requires that each validation report be reviewed, approved, signed, and dated by the laboratory supervisor or management employee. This is necessary because it enables the Bureau to ensure the head of the laboratory is reviewing the data and approving the method validation report while also placing responsibility of this approval on the head of the laboratory.

Proposed subsection (d)(8) requires the laboratory, upon using new test methods or altered test methods, to submit a new validation report to the Bureau within five business days. This is necessary because it enables the Bureau to ensure that the laboratory performs validation of new or altered test methods and submit the results in a compiled report to the Bureau for verification.

§ 5714. Required Testing

Proposed section 5714 enumerates the types of analyses that the laboratory must perform for each representative sample that the laboratory obtains from a distributor. These tests are necessary to ensure all cannabis goods sold pursuant to a license have passed testing for contaminants, potency, and terpenes, if applicable. This is a requirement under Business and Professions Code section 26100(a). The section also requires the laboratory to report the results of each analysis performed by the laboratory on the certificate of analysis (COA).

Proposed subsection (a)(1) requires the laboratory to analyze each representative sample it collects for the cannabinoid content. This is necessary to determine whether the cannabinoid content of the sample conforms to the labeled content of cannabinoids and is required under Business and Professions Code section 26100(d)(1).

Proposed subsection (a)(2) requires the laboratory to analyze each representative sample it collects for foreign material. This is necessary to determine whether the presence of foreign material exceeds the levels established by the Bureau and is required under Business and Professions Code section 26100(d)(2)(A).

Proposed subsection (a)(3) requires the laboratory to analyze each representative sample it collects for heavy metals. This is necessary to determine whether the presence of heavy metals exceeds the levels established by the Bureau. While the statute does not require testing of heavy metals specifically, the statute requires the laboratory to report the level of contaminants, as determined by the Bureau. The Bureau has determined that heavy metals are a contaminant potential present in cannabis goods and therefore is proposing to require testing of heavy metals.

Proposed subsection (a)(4) requires the laboratory to analyze each representative sample it collects for microbial impurities. This is necessary to determine whether the presence of microbial impurities exceeds the levels established by the Bureau and is required under Business and Professions Code section 26100(d)(2)(C).

Proposed subsection (a)(5) requires the laboratory to analyze each representative sample it collects for mycotoxins. Exposure to mycotoxins, toxics microbial substance produced by fungi, can result in serious harm. Under Business and Professions Code section 26100(d)(2)(C), the laboratory must test for microbial impurities as identified by the Bureau. The Bureau has identified that mycotoxins are a microbial contaminant potential present in cannabis goods, exposure to which may cause serious harm to patients and adult-use consumers of cannabis goods. As such, the Bureau proposes to require testing of mycotoxins.

Proposed subsection (a)(6) requires the laboratory to analyze each representative sample it collects for moisture content and water activity. Analysis of moisture content is necessary to determine the percent of water in a sample and is used to calculate potency. Analysis of water activity is necessary to determine the quantity of water that is available and therefore capable of supporting bacteria, yeasts, and fungi. These requirements are necessary to ensure that the level of moisture content and water activity do not exceed the levels established by the Bureau.

Proposed subsection (a)(7) requires the laboratory to analyze each representative sample it collects for residual pesticides. This is necessary to determine whether the presence of residual pesticides exceeds the levels established by the Bureau and is required under Business and Professions Code section 26100(e).

Proposed subsection (a)(8) requires the laboratory to analyze each representative sample it collects for residual solvents and processing chemicals. This is necessary to determine whether the presence of residual solvents and processing chemicals exceeds the levels established by the Bureau and is required under Business and Professions Code section 26100(d)(2)(A).

Proposed subsection (a)(9) requires the laboratory to analyze each representative sample it collects for terpenoids, if applicable. This is necessary to determine whether the terpenoid

content of the sample conforms to the labeled content of terpenoids and is required under Business and Professions Code section 26100(d)(1)(E).

Proposed subsection (a)(10) requires the laboratory to analyze each representative sample it collects for homogeneity, if applicable. This is necessary to determine whether the edible cannabis product being tested has consistent levels of THC throughout the product.

Proposed subsection (b) requires the laboratory to report the results of each test on the certificate of analysis (COA). This is a requirement under Business and Professional Code section 26100(d).

§ 5715. Phase-In of Required Laboratory Testing

Proposed section 5715 establishes the types of analysis that must be performed by the laboratory for each sample of cannabis product obtained from a distributor using phase-in dates. This is necessary to provide clarity to the industry on what needs to be tested. The proposed phase-in dates are based on the Bureau's laboratory survey, public comments, and our recommendations.

Proposed subsection (a) clarifies that cannabis goods shall not be sold or transferred to a retailer, or released for retail sale, unless a representative sample of the cannabis or cannabis product has undergone and passed all testing as required by this section. This is necessary to provide guidance and clarity to regulated public.

Proposed subsection (b) requires that all cannabis harvested on or after January 1, 2018, and all cannabis products manufactured on or after January 1, 2018, shall be tested for cannabinoids; moisture content; Category II residual solvents and processing chemicals; Category I residual pesticides; and microbiological impurities; mycotoxins. It is necessary to require these tests based on the Bureau's laboratory survey, public comments, and the Bureau's recommendations.

Proposed subsection (c) requires that in addition to the requirements of subsection (b) of this section, all cannabis harvested on or after July 1, 2018, and all cannabis products manufactured on or after July 1, 2018 for Category I residual solvents and processing chemicals; Category II residual pesticides; and foreign material. It is necessary to require these tests based on the Bureau's laboratory survey, public comments, and the Bureau's recommendations.

Proposed subsection (d) requires that in addition to the requirements in subsections (b) and (c) of this section, all cannabis harvested on or after December 31, 2018, and all cannabis products manufactured on or after December 31, 2018, shall be tested for terpenoids; mycotoxins; heavy metals; and water activity. It is necessary to require these tests based on the Bureau's laboratory survey, public comments, and the Bureau's recommendations.

Proposed subsection (e) specifies that a licensee may have a sample of cannabis goods tested for analytes that have not yet been phased-in. It further specifies that if a sample fails any additional test(s) that are not required on the date of testing, the batch from which it was collected fails testing and cannot be released for retail sale. This is necessary to establish the fate of batches that fail additional testing throughout the phase-in dates.

§ 5716. [reserved]

§ 5717. Moisture Content and Water Activity Testing

Proposed section 5717 requires testing of dried flower for water activity and moisture content before release of the batch for retail sale. Water activity and moisture content can be indicators of microbial growth, which can be harmful when present in certain cannabis goods, such as dried flower. Dried flower samples, including pre-rolls, shall have the moisture content measured as a quality indicator¹⁴, but shall not fail if the moisture content is measured as a high percentage. The water activity action levels proposed in this section are based on levels that help minimize the growth of harmful fungi and bacteria. The proposed testing is necessary to provide the patient/consumer with information on the quality of the cannabis and will help to ensure the cannabis or cannabis product can be stored without hazardous effects, and safe for the public consumption.

Proposed subsection (a) specifies that the testing laboratory must analyze at least 0.5 grams of the representative sample of dried flower to determine the water activity and moisture content. This is necessary to ensure that the laboratory tests an appropriate amount of each sample for moisture content and water activity. Furthermore, this requirement is necessary because cannabis test methods are not standardized, but requiring the laboratories to use the same minimum amount of sample to analyze for moisture content and water activity will provide equilibrium in sample analysis between the various laboratories. During the first 6 months of the emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. There is a requirement for the laboratories to obtain a representative sample, mandating that a minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories.

After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories.

¹⁴ digipathLabs, Moisture Residue Analysis (2015) <<http://digipathlabs.com/moisture-residue-analysis/>> (as of Mar. 28, 2017).

Proposed subsection (a)(1) specifies the action level for water activity in dried cannabis. Outdoor and indoor cultivations expose plants to a variety of conditions favorable to microbes throughout their growth. In cannabis flower production, microorganisms such as bacteria and mold are important quality issues. Water activity is the amount of available water in the cannabis that is accessible for microbial contaminants to use for growth.¹⁵ Cannabis can potentially harbor pathogenic bacteria and mold if the water activity level is above 0.65 and the microbes have had ample time to grow. A lower water activity value indicates that there is less available water and thus less opportunity for microbial contaminants to grow. Other states have set the same action level for water activity of cannabis.¹⁶¹⁷ This is necessary to ensure dried cannabis is safe for public consumption and poses no immediate health risks from microbial growth that may result from storage of the cannabis.

This subsection also requires the testing laboratory to report the water activity level of the cannabis sample on the certificate of analysis (COA) and indicate if the sample passed or failed water activity testing. This allows the receiver(s) of the COA to easily identify if the sample and the associated batch passed regulatory compliance testing for water activity. This is necessary for an efficient and streamlined method of testing and reporting.

Proposed subsection (a)(2) specifies that the cannabis sample shall have its moisture content tested and reported on the COA as a percentage. Water activity and moisture content are not interchangeable.¹⁸ Although water activity is a value of the available water in the material and an indicator for microbial growth, moisture content is the total amount of moisture in the material and indicates the quality of the cannabis, based on consumer preference. This is necessary to convey the quality of the cannabis being tested, and ensures consistent reporting.

Proposed subsection (b) specifies that the testing laboratory must analyze at least 0.5 grams of the representative sample of solid edible cannabis products to determine the water activity. During the first 6 months of the emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. There is a requirement for the laboratories to obtain a representative sample, mandating that a minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories.

¹⁵ Cannabis Safety Institute, Microbiological Safety Testing of Cannabis, May 2015.

<http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/Microbiological-Safety-Testing-of-Cannabis.pdf>. Accessed April 12, 2018.

¹⁶ Washington Administrative Code. WAC 314-55-102. Chapter 214-55. Liquor and Cannabis Board. Marijuana Licenses, Application Process, Requirements, and Reporting. Quality Assurance Testing.

¹⁷ Oregon Labs Technical Advisory Committee, *Meeting Summary and Recommendations for Cannabis Testing* (2015) State of Oregon.

https://www.oregon.gov/olcc/marijuana/Documents/Agendas/LABS_SummaryandRecommendations_070215.pdf Accessed March 28, 2017

¹⁸ Cannabis Safety Institute, Standards for Cannabis Testing Laboratories, December 2014. <http://cannabissafetyinstitute.org/wp-content/uploads/2015/01/Standards-for-Cannabis-Testing-Laboratories.pdf>. Accessed April 12, 2018.

After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories. Water activity is the amount of available water in the cannabis product that is accessible for microbial contaminants to use for growth. Cannabis products can support the growth of bacteria, yeasts, and mold if the water activity level is too high.¹⁹ The amount of available water can be reduced to a point that will inhibit the growth of the organisms. If the water activity of a food product is controlled at 0.85 A_w or below in the finished product, it is not subject to the FDA regulations in Title 21 (sections 108 regarding permits, 113 regarding thermally processed low-acid foods packaged in hermetically sealed containers, and 114 regarding acidified foods).²⁰ Solid edible cannabis products that have a water activity level of 0.85 A_w, or below, have less opportunity for microbial contaminants, based on this action level set by the FDA. This action level is necessary to ensure solid edible cannabis products are safe for public consumption and pose no immediate health risks from microbial growth that may result from storage of the cannabis product.

This subsection also requires the testing laboratory to report the water activity level of the cannabis product sample on the certificate of analysis (COA) and indicate if the sample passed or failed water activity testing. This is necessary because it allows the receiver(s) of the COA to easily identify if the sample and the associated batch passed regulatory compliance testing for water activity.

Proposed subsection (c) specifies that if the sample fails water activity testing, the batch from which the sample was taken may not be released for retail sale. This is necessary to establish the action that must be taken with samples and related batches that fail water activity testing.

§ 5718. Residual Solvents and Processing Chemicals Testing

Proposed subsection (a) requires the laboratory to analyze at minimum 0.5 grams of the representative sample of cannabis product, including pre-rolls, to determine whether residual solvents or processing chemicals are present. The purpose of this provision is to ensure that cannabis goods intended for human consumption and use do not contain residual solvents and processing chemicals more than the action levels established by the Bureau. This requirement is necessary to standardized testing procedures, in part, by requiring the laboratories to use the same minimum amount of sample to analyze for residual solvents and processing chemicals. Furthermore, during the first 6 months of the

¹⁹ Safefood 360°, Water Activity (a_w) in Foods, 2014. <http://safefood360.com/resources/Water-Activity.pdf>. Accessed April 12, 2018.

²⁰ US Food and Drug Administration, Dept. of Health Education, and Welfare Public Health Service, Water Activity (a_w) in Foods, Date: 4/16/84, Number: 39. <http://www.fda.gov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/ucm072916.htm>. Accessed April 12, 2018.

emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. There is a requirement for the laboratories to obtain a representative sample, mandating that a minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories.

After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories. The Bureau has determined that residual solvents and processing chemical testing is not necessary for dried flower. This is because dried flower is not subject to processing using solvents and are therefore not expected to contain residual solvents or processing chemicals.

Solvents are used to extract cannabinoids from dried flower in concentrated amounts. Processing chemicals are used in the processing and manufacturing production of cannabis products and may include machine operations and product packaging.²¹ When present in products intended for human consumption, excessive amounts of residual solvents and processing chemicals may pose risks to human health^{22,23,24,25,26}. Thus, this provision is necessary to ensure that cannabis products intended for human consumption and use do not contain residual solvents and processing chemicals more than the action levels established by the Bureau.

Proposed subsection (b) requires the laboratory to report the level of residual solvents and processing chemicals detected in a cannabis product sample in microgram per gram ($\mu\text{g/g}$)

²¹ 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 Jun. 7, 2018)

²² Office of Environmental Health Hazard Assessment (OEHHA), *OEHHA Acute, 8-hour and Chronic Reference Exposure Level (REL) Summary* (Jun. 2016) State of California <<https://oehha.ca.gov/air/general-info/oehha-acute-8-hour-and-chronic-reference-exposure-level-rel-summary>> (as of Oct. 4, 2017).

²³ Office of Environmental Health Hazard Assessment (OEHHA), Air Toxics Hot Spots Program, *Guidance Manual for Preparation of Health Risk Assessments*, State of California, Appendices L-6 and L-26

²⁴ 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 Jun. 7, 2018).

²⁵ EMD, Chloroform Material Safety Data Sheet (MSDS)

²⁶ Office of Environmental Health Hazard Assessment (OEHHA), *Hot Spots Unit Risk and Cancer Potency Values*, State of California <<https://oehha.ca.gov/media/CPFs042909.pdf>> (as of Oct. 4, 2017)

unit. This provision is necessary to create uniformity and consistency in reporting. Uniform and consistent reporting is necessary to enable both the Bureau and licensees to objectively compare the test results. In addition, this provision specifies that the laboratory must report the test results of the analysis of residual solvents and processing chemicals detected in a cannabis product sample on the certificate of analysis (COA) and indicate “pass” or “fail”. This requirement is necessary to ensure that the entity that requested the analytics be provided accurate and complete information about the samples tested.

Proposed subsection (c) requires the laboratory to establish a limit of quantification (LOQ) of 1.0 µg/g or lower for all Category I Residual Solvents or Processing Chemicals. Although the use of these solvents and processing chemicals are not specifically allowed for production of cannabis products, it is necessary to establish a minimum level to which all laboratories must be able to accurately quantitate.²⁷ By requiring the laboratories to achieve a minimum limit of quantification will provide equilibrium between the laboratories reporting abilities. This provision will also prevent licensed testing laboratories from establishing LOQs that result in samples passing the Category I Residual Solvents or Processing Chemicals whereas the same sample would otherwise fail if tested by a laboratory with an established lower LOQ.

Proposed subsection (d) contains tables that list the specific residual solvents and processing chemicals (Category I, and Category II), along with their respective action levels (Category II) of residual solvents and processing chemicals, for which a laboratory must analyze samples of cannabis products.^{28,29,30} This purpose of this subsection is to identify those specific residual solvents which must be tested in order for the cannabis good to meet the standards for safe consumption. This provision is necessary to clarify the Residual Solvent testing requirements set forth in these regulations.

Proposed subsection (d)(1) requires the laboratory to report that the sample of cannabis product passed residual solvents and processing chemicals test only if any residual solvents

²⁷ Department of Energy and Environmental Protection, *Guidance for Calculating the 95% Upper Confidence Level for Demonstrating Compliance with the Remediation Standard Regulations* (May 2014) State of Connecticut

<http://www.ct.gov/deep/lib/deep/site_clean_up/remediation_regulations/95ucl_guidance.pdf> (as of Jun. 7, 2018).

²⁸ 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 Jun. 7, 2018).

²⁹ California Division of Occupational Safety and Health (Cal/OSHA), *Permissible Exposure Limits (PELs) from Table AC-1, Table Z-1* (Jul. 7, 2016)

<<https://www.osha.gov/dsg/annotated-peis/tablez-1.html>> (as of Jun. 7, 2018).

³⁰ Division of Public and Behavioral Health, NAC 453A.592, *Authorized methods, equipment, solvents, gases and mediums* (Nov. 2015) State of Nevada

<<http://dpbh.nv.gov/uploadedFiles/dpbh.nv.gov/content/Reg/MedMarijuana/dta/Policies/MME022%20Residual%20Solvent%20Testing%20for%20Medical%20Marijuana%20Independent%20Laboratories.pdf>> (as of Jun. 7, 2018).

and processing chemicals listed in Category I table are not detected. This provision is necessary to clarify that a laboratory needs only to test and report for the specific residual solvents and processing chemicals listed in the Category I table, and what qualifies as passing for these specific residual solvents and processing chemicals. The Bureau has determined that residual solvents and processing chemicals in this category must not be detected in order to pass testing, as indicated below.

Proposed subsection (d)(2) clarifies that the laboratory must report that the sample of cannabis product passed residual solvents and processing chemicals test only if the concentrations of residual solvents and processing chemicals do not exceed the action levels established by the Bureau in Category II table. This provision is necessary to clarify that a laboratory needs only to test and report for the specific residual solvents and processing chemicals listed in the Category II table, and what qualifies as passing for these specific residual solvents and processing chemicals. The Bureau has determined that residual solvents and processing chemicals in this category must meet the stated action levels in order to pass testing, as indicated below.

Proposed subsection (d)(2)(A) specifies that notwithstanding subsection (d)(2) the limit for ethanol³¹ does not apply to cannabis goods that intended for tinctures. This provision is necessary to clarify that a laboratory may find test results exceeding the action levels for ethanol in such cannabis products intended for transdermal use, dermal use, or tinctures and that these products are essentially exempt from ethanol and isopropyl alcohol, but not the remaining residual solvents listed in category I and category II.

Category 1 Table. Highly toxic and Cancer Risk Chemicals³²

| Category I Residual Solvent or Processing Chemical | CAS No. |
|--|----------|
| 1,2-Dichloroethane | 107-06-2 |
| Benzene | 71-43-2 |
| Chloroform | 67-66-3 |
| Ethylene oxide | 75-21-8 |
| Methylene chloride | 75-09-2 |
| Trichloroethylene | 79-01-6 |

³¹ Sasol, *Ethanol Safety Data Sheet* (May 2015)

http://www.sasoltechdata.com/MSDS/SDA_3A_200.pdf Accessed Mar. 29, 2017

³² Occupational Safety and Health Administration, *Chemical Sampling Information, VM & P Naphtha (Petroleum ether)*, U.S. Department of Labor

<https://www.osha.gov/dts/chemicalsampling/data/CH_274955.html> (as of Mar. 29, 2017).

Category 2 Table. The action levels of residual solvents and processing chemicals for inhalable cannabis products and other cannabis products

| Category II Residual Solvent or Processing Chemical | CAS No. | Cannabis Products Action Level (µg/g) |
|--|----------------|--|
| Acetone | 67-64-1 | 1000 |
| Acetonitrile | 75-05-8 | 80 |
| Butane | 106-97-8 | 1000 |
| Ethanol | 64-17-5 | 1000 |
| Ethyl acetate | 141-78-6 | 1000 |
| Ethyl ether | 60-29-7 | 1000 |
| Heptane | 142-82-5 | 1000 |
| Hexane | 110-54-3 | 60 |
| Isopropyl alcohol | 67-63-0 | 1000 |
| Methanol | 67-56-1 | 600 |
| Pentane | 109-66-0 | 1000 |
| Propane | 74-98-6 | 1000 |
| Toluene | 108-88-3 | 180 |
| Total xylenes (ortho-, meta-, para-) | 1330-20-7 | 430 |

Proposed subsection (e) specifies that if a sample fails residual solvents and processing chemical test, the batch from which the sample was taken may not be sold or released by a distributor for retail sale. This provision is necessary to protect the consumers from the failed products.

Determination of recommended residual solvents and processing chemicals for test

In determining which residual solvents^{33,34,35} and processing chemicals to require a laboratory test for, the Bureau surveyed the cannabis laboratory testing standards in Colorado³⁶, Massachusetts³⁷, Nevada³⁸, and Washington³⁹. The Bureau also conducted online research to determine the most common solvents and processing chemicals used in the cannabinoids extraction process⁴⁰. Finally, the Bureau received information from California laboratories on the types of solvents and processing chemicals that are routinely detected in cannabis products.

Determination of recommended action levels

In determining the acceptable action levels for each residual solvent and processing chemical listed, the action levels adopted by other jurisdictions were researched as well as those established by the Office of the Environmental Health Hazard Assessment (OEHHA)⁴¹, the United States Environmental Protection Agency (USEPA)⁴², the Agency for Toxic Substances and Disease Registry (ATSDR)⁴³, California Division of

³³ U.S. Environmental Protection Agency (US EPA), *Integrated Risk Information System (IRIS)*, *Chemical Assessment Summary, Acetonitrile; CASRN 75-05-8* <https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0205_summary.pdf> (as of Oct. 5, 2017).

³⁴ U.S. Environmental Protection Agency (US EPA), *Integrated Risk Information System (IRIS)*, *Chemical Assessment Summary National Center for Environmental Assessment, Xylenes; CASRN 1330-20-7* <https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0270_summary.pdf> (as of Oct. 5, 2017).

³⁵ U.S. Environmental Protection Agency (US EPA), *Integrated Risk Information System (IRIS)*, *Chemical Assessment Summary National Center for Environmental Assessment, n- Hexane; CASRN 110-54-3* <https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0486_summary.pdf> (as of Oct. 5, 2017).

³⁶ Colorado Administrative Code section 212-2.712. State of Colorado. Code of Colorado Regulations. <https://www.colorado.gov/pacific/sites/default/files/Retail%20Marijuana%20Rules%20through%2001302015.pdf>

³⁷ Massachusetts State. Department of Public Health. Bureau of Health Care Safety and Quality. Medical Use of Marijuana Program. Exhibit 7(a) Concentration Limits for Residual Solvents. <http://www.mass.gov/eohhs/docs/dph/quality/medical-marijuana/lab-protocols/finished-mmj/final-exhibit-7-residual-solvent-limits.pdf>

³⁸ Nevada Administrative Code section 453A.592. Authorized methods, equipment, solvents, gases and mediums. <http://dpbh.nv.gov/uploadedFiles/dpbh.nv.gov/content/Reg/MedMarijuana/dta/Policies/MME022%20Residual%20Solvent%20Testing%20for%20Medical%20Marijuana%20Independent%20Laboratories.pdf>

³⁹ Washington State Legislature. WAC 314-55-104. Marijuana processor license extraction requirements. <http://app.leg.wa.gov/WAC/default.aspx?cite=314-55-104>

⁴⁰ Cannabis Cure Team. Making Cannabis Oil. <http://www.cannabiscure.info/cannabis-oil/>

⁴¹ Office of the Environmental Health Hazard Assessment (OEHHA). <https://oehha.ca.gov/>

⁴² United States Environmental Protection Agency (USEPA) <https://www.epa.gov/>

⁴³ Agency for Toxic Substances and Disease Registry (ATSDR) <https://www.atsdr.cdc.gov/>

Occupational Safety and Health (Cal/OSHA)⁴⁴, and the United States Pharmacopeial Convention (USP)⁴⁵⁴⁶.

Considering the standards adopted by other states, federal standards⁴⁷, and industry guidelines, alongside the critical health risks of contaminants from cannabis products to consumers, it was determined that two groups of categorizations were necessary:

Category I includes six chemicals including: 1,2-dichloroethane, benzene, chloroform, ethylene oxide, methylene chloride, and trichloroethylene. These chemicals are considered unacceptable substances to use due to their toxicity and carcinogenic effects and should not be used in the production of cannabis products. If these chemicals are detected in the test of both inhalable cannabis products and other cannabis products, the cannabis product batch which the sample was taken should be rejected.

When a laboratory reports results for any analytes that were not detected or that were below the LOD for analytes in Category I, the laboratory must indicate “ND” for Not Detected on the COA. LOD is matrix, method, and analyte specific. Each laboratory must establish their own method per each required test with associated validation proof. Based on each laboratory’s validated method, each lab needs to calculate the LOD per each analyte (i.e. signal-to-noise ratio, standard deviation of the response in spiked samples or standards, and the slope of calibration curve, etc.) and establish a LOQ of 1.0 ug/g or lower for all Category I Residual Solvents or Processing Chemicals. Testing laboratories can refer to EPA or FDA for guidance when determining LOD. LODs should be reasonable based on the validated test method, instrument, the range of the standards, etc. The Bureau will be reviewing the licensed laboratories test methods SOPs and validation SOPs, which will include reviewing LOD and LOQ determinations.

Category II includes 14 chemicals including: Acetone, Acetonitrile, Butane, Ethanol, Ethyl acetate, Ethyl ether, Heptane, Hexane, Isopropyl alcohol, Methanol, Pentane⁴⁸, Propane⁴⁹, Toluene, and Total xylenes (ortho-, meta-, para-). Action levels were set for Category II by

⁴⁴ California Division of Occupational Safety and Health (Cal/OSHA) <http://www.dir.ca.gov/DOSH/>

⁴⁵ The U.S. Pharmacopeial Convention. *USP Revision Bulletin Official: Articles of Botanical Origin* (Aug. 2014) <http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/gc_561.pdf> (as of Mar. 30, 2017).

⁴⁶ The U.S. Pharmacopeial Convention, U.S. Pharmacopeia, Residual Solvents, Chapter 467 <<https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c467.pdf>> (as of Mar. 29, 2017).

⁴⁷ National Institute for Occupational Safety and Health (NIOSH), *NIOSH Pocket Guide to Chemical Hazards* (Sept. 2007) pp. 35, 131, 132, 140, 157, 244, 263

<<https://www.cdc.gov/niosh/docs/2005-149/pdfs/2005-149.pdf>> Accessed Oct. 5, 2017

⁴⁸ National Institute for Occupational Safety and Health (NIOSH), *Pentane* (1988) <<https://www.cdc.gov/niosh/pel88/109-66.html>> (as of Mar. 29, 2017).

⁴⁹ National Institute for Occupational Safety and Health (NIOSH), *Propane* (1994) <<https://www.cdc.gov/niosh/idlh/74986.html>> (as of Mar. 29, 2017).

using the United States Pharmacopeial Convention (USP)⁵⁰ action levels with a fivefold safety factor. This safety factor was used to account for rapid absorption via inhalation versus ingestion and to account for the possibility of multiple solvents in the concentrate.

§ 5719. Residual Pesticides Testing

Pesticides may be used during the cultivation of cannabis and may be further concentrated when cannabis with residual pesticides are used to create manufactured products. When present in products intended for human consumption, residual pesticides may pose risks to human health. The purpose of this provision is to ensure that cannabis goods intended for human consumption and use do not contain residual pesticides more than the action levels established by the Bureau.

Proposed subsection (a) requires the laboratory to analyze at minimum 0.5 grams of the representative sample of cannabis or cannabis product for residual pesticides. This is to provide clarity and consistency to licensed laboratories, and will help in creating a streamlined and efficient method of testing for residual pesticides.

This requirement is necessary because cannabis test methods are not standardized, but requiring the laboratories to use the same minimum amount of sample to analyze for residual pesticides will provide equilibrium in sample analysis between the various laboratories. The Bureau has determined that 0.5 grams is the minimum amount necessary to provide such consistency and equilibrium. Furthermore, during the first 6 months of the emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. There is a requirement for the laboratories to obtain a representative sample, mandating that a minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories. After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories.

⁵⁰ USP (U.S. Pharmacopeia) home. <http://www.usp.org/>

Proposed subsection (b) specifies that the testing laboratory must report the level of residual pesticides detected in a cannabis or cannabis product sample in microgram per gram ($\mu\text{g/g}$) units. This is to provide clarity to licensed laboratories on how to report in a uniform and consistent manner, and will help in creating a streamlined and efficient method of testing and reporting for residual pesticides. Uniform and consistent reporting is necessary to enable both the Bureau and licensees to objectively compare the test results. In addition, this provision specifies that the laboratory must report the test results of the analysis of residual pesticides detected in a cannabis sample or cannabis product sample on the certificate of analysis (COA) and indicate “pass” or “fail”. This requirement is necessary to ensure that the entity that requested the analytics be provided accurate and complete information about the samples tested.

Proposed subsection (c) specifies that the laboratory shall establish a limit of quantification (LOQ) of 0.10 $\mu\text{g/g}$ or lower for all Category I Residual Pesticides. Although use of these pesticides at any level is not permitted, as they are not allowed for use in the cultivation of cannabis, it is necessary to have a minimum level that all labs must be able to quantitate accurately. Cannabis test methods are not standardized, but requiring the laboratories to achieve a minimum limit of quantification will provide equilibrium between the laboratories reporting abilities. This provision will also prevent licensed testing laboratories from having higher LOQs and passing samples that would fail from a laboratory with lower LOQs. 0.10 $\mu\text{g/g}$ was determined to be the most appropriate minimum LOQ, as this is the lowest action level in Category II Residual Pesticides. If laboratories are required to determine if a sample has passed based on a 0.10 $\mu\text{g/g}$ action level, at a minimum the laboratories LOQ for Category II Residual Pesticides is also 0.10 $\mu\text{g/g}$.

Subsection (d) contains tables that list the specific residual pesticides (Category I, and Category II), along with their respective action levels (Category II) for which a laboratory must analyze samples of cannabis goods. The purpose of this subsection is to inform laboratories performing required testing, of the specific residual pesticides that need to be tested, and the results that need to be obtained in order for a sample to pass testing. This is necessary to create uniformity and consistency, and establish guidelines for certain residual pesticides, as some may be more harmful than others.

Proposed subsection (d)(1) makes clear that a laboratory must report that the sample of cannabis product passed residual pesticide testing only if any pesticides listed in Category I table are not detected. The purpose of this subsection is to establish the limit for which these residual pesticides may be present in order to pass testing. This provision is necessary to clarify that a laboratory needs only to test and report for the specific residual pesticides listed in the Category I table, and what qualifies as passing for these specific residual pesticides. The Bureau has determined that residual pesticides in this category must not be detected in order to pass testing, based on recommendation of DPR, as indicated below.

Proposed subsection (d)(2) makes clear that a laboratory must report that the sample of cannabis or cannabis product passed residual pesticide testing only if the concentrations of residual pesticides do not exceed the action levels established by the Bureau in Category II table. The purpose of this subsection is to establish the limit for which these residual pesticides may be present in order to pass testing. This provision is necessary to clarify that a laboratory needs only to test and report for the specific residual solvents and processing chemicals listed in the Category II table, and what qualifies as passing for these specific residual pesticides. The Bureau has determined that residual pesticides in this category must not exceed the stated action levels, based on the recommended levels provided by DPR, as indicated below.

Proposed subsection (e) proposes that if the sample fails pesticide testing, the batch from which the sample was taken may not be sold or released by a dispensary for retail sale. This will ensure that consumers and the public will not be exposed to unsafe and harmful cannabis goods. This provision is necessary to protect the consumers from the failed products. Every failed batch must be returned to the requester and should be held until further actions are taken, which are specified in the testing laboratory regulations.

This list is composed of 66 pesticide active ingredients currently used on cannabis. It was compiled from information collected in Colorado, Oregon, Washington, Nevada, and California and encompasses news articles^{51,52,53,54} test results, regulatory guidelines,^{55,56} and anecdotal information from cannabis cultivators and state regulators. DPR then divided the listed pesticides into two broad categories:

⁵¹ David Migoya and Ricardo Baca. October 2, 2016. “State issues massive recall of pesticide-tainted marijuana.” *Denver Post*. <http://www.denverpost.com/2016/03/17/state-issues-massive-recall-of-pesticide-tainted-marijuana/>. Accessed on April 4, 2017.

⁵² Alicia Lozano. October 27, 2016. “Pesticides in cannabis pose a growing problem for cannabis consumers.” *LA Weekly*. <http://www.laweekly.com/news/pesticides-in-marijuana-pose-a-growing-problem-for-cannabis-consumers-7526808>. Accessed on April 4, 2017.

⁵³ Melia Robinson. December 15, 2016. “Marijuana can be covered in pesticides, fungi, and mold—even if it’s legal.” *Business Insider*. <http://www.businessinsider.com/marijuana-bacteria-contamination-health-concerns-2016-12>. Accessed on April 4, 2017.

⁵⁴ Matthew Glasser and Joel Grover. February 22, 2017. “Pesticides and pot: lab results, company statements.” <http://www.nbclosangeles.com/news/local/Pesticide-Laced-Pot-Lab-Results-Company-Statements-I-Team-414526923.html>. Accessed on April 4, 2017.

⁵⁵ Cannabis Safety Institute. *Pesticide Use on Cannabis*. June 2015. <http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/CSI-Pesticides-White-Paper.pdf>. Accessed on April 4, 2017.

⁵⁶ Farrer DG. *Technical Report: Oregon Health Authority’s Process to Decide Which Types of Contaminants to Test for in Cannabis*. Oregon Health Authority. 2015 December. <https://public.health.oregon.gov/PreventionWellness/marijuana/Documents/oha-8964-technical-report-marijuana-contaminant-testing.pdf>. Accessed on April 4, 2017.

Category I: pesticides with the maximum allowable limit set above the minimum detection limit used by the California Pesticide Residue Monitoring Program.

Category II: pesticides with the maximum allowable limit set above the minimum detection limit of the California Pesticide Residue Monitoring Program and based on human-health considerations for the different consumption categories.

Category I: Includes pesticides that DPR identifies as having human health or environmental concerns. DPR determined that 21 of the listed pesticides fall under this category based on at least one of the following human health or environmental concerns:

High Acute Toxicity: Pesticides with high acute toxicity are hazardous to human health when consumed.

Ground Water Protection List: DPR lists pesticides with chemical characteristics that make them likely to move into groundwater on the Groundwater Protection List at section 6800(b) in Title 3 of the California Code of Regulations. DPR is concerned about the potential environmental impacts to groundwater caused by the use of these pesticides for cannabis cultivation.

Neonicotinoid: Neonicotinoids are a class of pesticides. The federal Environmental Protection Agency (US EPA) has stopped new registrations of neonicotinoid pesticides pending a determination about potential impacts to pollinators. DPR is concerned about the potential environmental impacts to pollinators caused by the use of these pesticides for cannabis cultivation.

Restricted Materials: DPR designates certain pesticides as “restricted materials” if they have a higher potential to cause harm to public health, farm workers, domestic animals, honeybees, the environment, wildlife, or other crops as compared to other pesticides. DPR is concerned about potential human health and environmental impacts caused by the use of restricted materials on cannabis.

Not Registered in California: Pesticides that are not registered for use in California. DPR has not approved these pesticides for any use in California.

No Food Uses: Pesticides that are not registered for any food use sites in California. Because these products have not been approved for use on food crops there has been no analysis of levels that are safe for human consumption.

Category I Pesticides:

| Category I Residual Pesticide | CAS No. |
|--|----------------|
| Aldicarb | 116-06-3 |
| Carbofuran | 1563-66-2 |
| Chlordane | 57-74-9 |
| Chlorfenapyr | 122453-73-0 |
| Chlorpyrifos | 2921-88-2 |
| Coumaphos | 56-72-4 |
| Daminozide | 1596-84-5 |
| DDVP (Dichlorvos) | 62-73-7 |
| Dimethoate | 60-51-5 |
| Ethoprop(hos) | 13194-48-4 |
| Etofenprox | 80844-07-1 |
| Fenoxy carb | 72490-01-8 |
| Fipronil | 120068-37-3 |
| Imazalil | 35554-44-0 |
| Methiocarb | 2032-65-7 |
| Methyl parathion | 298-00-0 |
| Mevinphos | 7786-34-7 |
| Paclobutrazol | 76738-62-0 |
| Propoxur | 114-26-1 |
| Spiroxamine | 118134-30-8 |
| Thiacloprid | 111988-49-9 |

For these pesticides DPR recommends the most stringent residue level—the level of detection. That is, a sample fails if one of these analytes is found at or above the detection level.

Category II: The remaining 45 pesticides are listed below. For these pesticides, DPR recommends maximum allowable residue levels in cannabis that are above the minimum limit of detection of the California Pesticide Residue Monitoring Program, based on

human-health considerations for each of the consumption categories.⁵⁷ That is, a sample fails if one of these analytes is found at a level above those listed here. DPR recommends differentiating between forms of consumption because each has unique human health considerations that currently cannot be addressed under a single level.

Edible cannabis products: DPR scientists calculated the levels using the method used in the PRMP to evaluate potential health risks from illegal pesticide residue detected on raw produce. The maximum residue level is calculated by using the lowest available reference dose (RfDs)—the daily exposure to the human population that is likely to be without an appreciable risk of deleterious effects—together with an estimated daily maximum consumption rate. The consumption rate is 100 grams per kilogram of body weight⁵⁸ (100 g/kg). DPR used this consumption rate as a surrogate for the actual rate of consumption for edible cannabis products. This rate is currently used for human health evaluations made under the PRMP.

Dried cannabis flower: DPR used tobacco as a surrogate based on the similar patterns of smoke inhalation. Levels for dried cannabis flower are based on one of the following:

Guidance Residue Levels (GRLs) established by the Centre Coopération pour les Recherches Scientifiques Relatives au Tabac (CORESTA), an organization established under French law to promote international cooperation in scientific research relative to tobacco and its derived products; or

US EPA registration data guidelines, which waive the requirement that pesticide registrants submit pyrolysis data to US EPA's Health Effects Division as part of an application to register a pesticide product for use on tobacco when the expected residue level on the tobacco at the time of harvest is less than 0.1 ppm. This indicates that US EPA does not believe that there is any reviewable acute health effect caused by inhaling tobacco smoke with less than 0.1 ppm of pesticide residue.

Other processed cannabis products: DPR used the pesticide-specific tolerance for either cottonseed oil or the lowest available tolerance for that active ingredient based on the assumption that manufacturing cottonseed oil is similar to manufacturing cannabis concentrates. Due to the lack of available information on cannabis consumption using a vape machine, none of the levels is above the lowest recommended level for dried cannabis flower used for smoking. These levels are intended only to address the human health effects of pesticide residue on processed cannabis.

⁵⁷ Chief Deputy Director Department of Pesticide Regulation, Theresa Marks, Memorandum, *Recommended Guidelines for Pesticide Residue in Processed Cannabis Products* (2017).

⁵⁸ McDowell, M.A., et al. *Anthropometric Reference Data for Children and Adults: United States, 2003–2006* (Oct. 2008) National Health Statistics Reports, No. 10

<https://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf> Accessed Oct. 4, 2017.

Category II Pesticides:

| Category II Residual Pesticide | CAS No. | Action Level ($\mu\text{g/g}$) | |
|-----------------------------------|-------------|----------------------------------|----------------------|
| | | Inhalable Cannabis Goods | Other Cannabis Goods |
| Abamectin | 71751-41-2 | 0.1 | 0.3 |
| Acephate | 30560-19-1 | 0.1 | 5 |
| Acequinocyl | 57960-19-7 | 0.1 | 4 |
| Acetamiprid | 135410-20-7 | 0.1 | 5 |
| Azoxystrobin | 131860-33-8 | 0.1 | 40 |
| Bifenazate | 149877-41-8 | 0.1 | 5 |
| Bifenthrin | 82657-04-3 | 3 | 0.5 |
| Boscalid | 188425-85-6 | 0.1 | 10 |
| Captan | 133-06-2 | 0.7 | 5 |
| Carbaryl | 63-25-2 | 0.5 | 0.5 |
| Chlorantraniliprole | 500008-45-7 | 10 | 40 |
| Clofentezine | 74115-24-5 | 0.1 | 0.5 |
| Cyfluthrin | 68359-37-5 | 2 | 1 |
| Cypermethrin | 52315-07-8 | 1 | 1 |
| Diazinon | 333-41-5 | 0.1 | 0.2 |
| Dimethomorph | 110488-70-5 | 2 | 20 |
| Etoxazole | 153233-91-1 | 0.1 | 1.5 |
| Fenhexamid | 126833-17-8 | 0.1 | 10 |
| Fenpyroximate | 111812-58-9 | 0.1 | 2 |
| Flonicamid | 158062-67-0 | 0.1 | 2 |
| Fludioxonil | 131341-86-1 | 0.1 | 30 |
| Hexythiazox | 78587-05-0 | 0.1 | 2 |
| Imidacloprid | 138261-41-3 | 5 | 3 |

| | | | |
|-----------------|-------------|-----|---|
| Kresoxim-methyl | 143390-89-0 | 0.1 | 1 |
|-----------------|-------------|-----|---|

| Category II Residual Pesticide | CAS No. | Action Level ($\mu\text{g/g}$) | |
|-----------------------------------|-----------------------------|----------------------------------|----------------------|
| | | Inhalable Cannabis Goods | Other Cannabis Goods |
| Malathion | 121-75-5 | 0.5 | 5 |
| Metalaxyl | 57837-19-1 | 2 | 15 |
| Methomyl | 16752-77-5 | 1 | 0.1 |
| Myclobutanil | 88671-89-0 | 0.1 | 9 |
| Naled | 300-76-5 | 0.1 | 0.5 |
| Oxamyl | 23135-22-0 | 0.5 | 0.2 |
| Pentachloronitrobenzene | 82-68-8 | 0.1 | 0.2 |
| Permethrin | 52645-53-1 | 0.5 | 20 |
| Phosmet | 732-11-6 | 0.1 | 0.2 |
| Piperonylbutoxide | 51-03-6 | 3 | 8 |
| Prallethrin | 23031-36-9 | 0.1 | 0.4 |
| Propiconazole | 60207-90-1 | 0.1 | 20 |
| Pyrethrins | 8003-34-7 | 0.5 | 1 |
| Pyridaben | 96489-71-3 | 0.1 | 3 |
| Spinetoram | 187166-15-0, 187166-40-1 | 0.1 | 3 |
| Spinosad | 131929-60-7, 131929-63-0 | 0.1 | 3 |
| Spiromesifen | 283594-90-1 | 0.1 | 12 |
| Spirotetramat | 203313-25-1 | 0.1 | 13 |
| Tebuconazole | 107534-96-3 | 0.1 | 2 |
| Thiamethoxam | 153719-23-4 | 5 | 4.5 |
| Trifloxystrobin | 141517-21-7 | 0.1 | 30 |

§ 5720. Microbial Impurities Testing

Proposed section 5720 requires the testing laboratory to test all cannabis good samples for specified microbial impurities. This proposed section establishes the type of microbial contaminants that inhalable cannabis goods and non-inhalable cannabis goods must be tested for and establishes the corresponding action levels. It is necessary for the Bureau to establish the microbial impurities that must be tested for in each sample and establish corresponding action levels to ensure the cannabis goods can be consumed without harmful results on the consumer's health. The benefit of this section is that cannabis goods will be tested for harmful microbial impurities and any cannabis goods that do not pass testing will not be transported to retail and sold to consumers thereby protecting the health and safety of the consumer.

Proposed subsection (a) specifies that the testing laboratory must analyze 1.0 gram of the representative sample of cannabis or cannabis products to identify if microbial impurities are present.⁵⁹ This is necessary to ensure that the laboratory tests an appropriate amount of each cannabis sample for microbial impurities. Furthermore, this requirement is necessary because cannabis test methods are not standardized, but requiring the laboratories to use the same minimum amount of sample to analyze for microbial impurities will provide equilibrium in sample analysis between the various laboratories. Furthermore, during the first 6 months of the emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. 1.0 gram was determined to be the most appropriate sample size for this method because of the action level requirement - a sample shall pass if no microbial impurities are detected in 1 gram. There is a requirement for the laboratories to obtain a representative sample, mandating that a minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories. After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories.

Proposed subsection (b) specifies that the testing laboratory shall indicate the results of the microbial impurities testing for the sample by designating a pass or fail on that sample's COA. The laboratory must report whether or not these bacteria are present in the sample. This is necessary because it allows the receiver(s) of the COA to easily identify the results

⁵⁹ 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 Jun. 7, 2018)

from microbial testing and to identify if the sample and the associated batch passed regulatory compliance testing.

Proposed subsection (c) enumerates the conditions that need to be met for the sample of inhalable cannabis goods to pass the microbial impurities testing. This is necessary because it outlines the various conditions that a sample needs to meet in order for the testing laboratory to pass the sample.

Proposed subsection (c)(1) requires that the presence of Shiga toxin-producing *Escherichia coli* (STEC) shall be tested for in all inhalable cannabis goods samples. STEC strains are of particular concern, as a low infection dose is capable of causing disease in both healthy and immunocompromised individuals by producing a toxin called Shiga toxin.⁶⁰ The immunocompromised population is more likely to develop the severe illness called hemolytic uremic syndrome. Because of the low infectious dose required for disease causation, there is zero tolerance for the presence of any STEC in all inhalable cannabis goods. The presence of STEC shall not be detected in 1 gram, based on levels recommended by the American Herbal Pharmacopeia,⁶¹ other states' regulations,⁶² and the Cannabis Safety Institute's report on microbiological safety testing.⁶³ This is necessary to establish the acceptance criteria for the sample to pass for STEC testing.

Proposed subsection (c)(2) requires that the presence of bacteria in the genus *Salmonella* shall be tested for in all inhalable cannabis goods samples. *Salmonella* is capable of causing gastrointestinal disease in both healthy as well as immunocompromised hosts.⁶⁴ Because of the low infectious dose required for disease causation, there is zero tolerance for the presence of any *Salmonella* in all inhalable cannabis goods. The presence of *Salmonella* shall not be detected in 1 gram, based on levels recommended by other states' regulations⁶⁵ and the Cannabis Safety Institute's report on microbiological safety testing.⁶⁶ This is necessary to establish the acceptance criteria for the sample to pass for *Salmonella* testing.

⁶⁰ Charles Kaspar, M. Ellin Doyle, and John Archer. *White Paper on Non-O157:H7 Shiga Toxin-Producing E. coli from Meat and Non-Meat Sources*. Fri Food Safety Reviews. April 2010. Pages 2-4. Available at: https://fri.wisc.edu/files/Briefs_File/FRI_Brief_NonO157STEC_4_10.pdf. Accessed April 16, 2018.

⁶¹ Roy Upton, Mahmoud ElSohly et.al. *Cannabis Inflorescence Cannabis spp. Standards of Identity, Analysis, and Quality Control*. Scott's Valley, CA: American Herbal Pharmacopeia; 2013. Book must be purchased to be accessed.

⁶² Washington Administrative Code. WAC 314-55-102. Chapter 214-55. Liquor and Cannabis Board. Marijuana Licenses, Application Process, Requirements, and Reporting. Quality Assurance Testing.

⁶³ Cannabis Safety Institute. *Microbiological Safety Testing of Cannabis*. May 2015. Pages 4-5,16. Available at: <http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/Microbiological-Safety-Testing-of-Cannabis.pdf>. Accessed April 16, 2018.

⁶⁴ Center for Disease Control and Prevention. *Salmonella*. CDC.

<https://www.cdc.gov/salmonella/general/index.html>. Accessed April 16, 2018.

⁶⁵ Washington Administrative Code. WAC 314-55-102. Chapter 214-55. Liquor and Cannabis Board. Marijuana Licenses, Application Process, Requirements, and Reporting. Quality Assurance Testing.

⁶⁶ Cannabis Safety Institute. *Microbiological Safety Testing of Cannabis*. May 2015. Pages 4-5,16. Available at: <http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/Microbiological-Safety-Testing-of-Cannabis.pdf>. Accessed April 16, 2018.

Proposed subsection (c)(3) specifies that the laboratory is required to test for specific fungal pathogenic *Aspergillus* species in all inhalable cannabis goods samples. *Aspergillus* is a genus of mold that causes aspergillosis and lung infections that can spread throughout the body in immunocompromised hosts.^{67,68} There are approximately 180 species of *Aspergillus*, but only a few are known to cause infections in humans.⁶⁹ The species that the Bureau proposes required testing for are *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus*⁷⁰. *Aspergillus fumigatus* is the most frequent species to cause invasive fungal infections in immunosuppressed individuals, including immunosuppressive therapy patients, autoimmune individuals, organ transplant recipients, and AIDS patients. *A. fumigatus* has been well documented as the invasive agent in cannabis patients affected with pulmonary aspergillosis.⁷¹⁷² *Aspergillus flavus* is also known for its pathogenicity in humans. *A. flavus* is an opportunistic pathogen, causing pulmonary aspergillosis in immunocompromised individuals. In addition, many *A. flavus* strains produce toxic compounds, known as mycotoxins, that are harmful to humans. *A. flavus* has been shown to be a significant contaminant of cannabis.⁷³ *Aspergillus niger*⁷⁴ is another one of the most common pathogenic species of the genus. This fungal species is ubiquitous in soil and is also commonly reported from indoor environments. Some strains of *A. niger* have been reported to produce mycotoxins. When inhaled, each of these four *Aspergillus* species are known to cause a variety of lung disorders, ranging from asthma, allergic bronchopulmonary aspergillosis, and hypersensitivity pneumonitis to invasive systemic fungal infections in immunocompromised hosts. The association between cannabis use and pulmonary aspergillosis has been documented in a number of clinical cases involving

⁶⁷ 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-articulo-cystic-fibrosis-atopy-asthma-abpa-S0301054610001515> (as of Jun. 7, 2018).

⁶⁸ Kagen, S.L., et al., *Marijuana Smoking and Fungal Sensitization* (Apr. 1983) Journal of Allergy and Clinical Immunology, 71(4):389-393. <[http://jacionline.org/article/0091-6749\(83\)90067-2/pdf](http://jacionline.org/article/0091-6749(83)90067-2/pdf)> (as of Jun. 7, 2018).

⁶⁹ Center for Disease Control and Prevention. Sources of Aspergillosis. CDC.

<https://www.cdc.gov/fungal/diseases/aspergillosis/causes.html>. Accessed April 16, 2018.

⁷⁰ Oregon Labs Technical Advisory Committee, *Meeting Summary and Recommendations for Cannabis Testing* (2015) State of Oregon.

https://www.oregon.gov/olcc/marijuana/Documents/Agendas/LABS_SummaryandRecommendations_070215.pdf Accessed March 28, 2017

⁷¹ Cescon DW, Page AV, Richardson S, Moore MJ, Boerner S, Gold WL. Invasive Pulmonary Aspergillosis Associated with Marijuana Use in a Man with Colorectal Cancer. Journal of Clinical Oncology. 2008;26(13):2214-2215. <http://ascopubs.org/doi/pdf/10.1200/JCO.2007.15.2777>. Accessed March 29, 2017.

⁷² Sutton S., et al., Possible Risk of Invasive Pulmonary Aspergillosis with Marijuana Use During Chemotherapy for Small Cell Lung Cancer (1986) Drug Intelligence and Clinical Pharmacy, 20(4):289-291.

⁷³ Paul E. Verweij, Jos J. Kerremans, Andreas Voss. Fungal contamination of tobacco and marijuana. JAMA. 2000;284(22):2875. <http://jamanetwork.com/journals/jama/fullarticle/1031109>. Accessed March 29, 2017.

⁷⁴ Schuster E., et al., *On the Safety of Aspergillus niger – a Review* (Apr. 2002) Applied Microbiology and Biotechnology, 59(4):426-435

[\(Accessed Mar. 28, 2017\)](https://www.researchgate.net/publication/11213736_On_the_safety_of_Aspergillus_niger_-A_review)

immunocompromised hosts.^{75,76,77} *Aspergillus* is not infectious when the route of administration is oral consumption, such as in the case of cannabis edibles or tinctures. The appropriate action level has been proposed that no specified *Aspergillus* spp. shall be detected in 1 gram of inhalable cannabis goods. This is necessary to establish the acceptance criteria for the sample to pass for *Aspergillus* spp. testing.

Proposed subsection (d) enumerates the conditions that need to be met for a sample of non-inhalable cannabis goods to pass the microbial impurities testing. This proposal is necessary because it lays out the various conditions that a sample needs to meet in order for the testing laboratory to pass the sample.

Proposed subsection (d)(1) requires that the presences of Shiga toxin-producing *Escherichia coli* (STEC) shall be tested for in all non-inhalable cannabis samples. STEC strains are of particular concern, as a low infection dose is capable of causing disease in both healthy and immunocompromised individuals by producing a toxin called Shiga toxin.⁷⁸ The immunocompromised population is more likely to develop the severe illness called hemolytic uremic syndrome. Because of the low infectious dose required for disease causation, there is zero tolerance for the presence of any STEC in all non-inhalable cannabis goods. The appropriate action level has been determined by the Bureau to be that no STEC shall be detected in 1 gram, based on levels recommended by the American Herbal Pharmacopeia,⁷⁹ other states' regulations,⁸⁰ and the Cannabis Safety Institute's report on microbiological safety testing.⁸¹ This is necessary to establish the acceptance criteria for the sample to pass for STEC testing.

Proposed subsection (d)(2) requires that the presence of bacteria in the genus *Salmonella* shall be tested for in all non-inhalable cannabis samples. *Salmonella* is capable of causing

⁷⁵ Center for Disease Control and Prevention. Sources of Aspergillosis. CDC.

<https://www.cdc.gov/fungal/diseases/aspergillosis/causes.html>. Accessed April 16, 2018.

⁷⁶ Yousef Gargani, Paul Bishop, and David W. Denning. Too many mouldy Joints – Marijuana and Chronic Pulmonary Aspergillosis. Mediterranean Journal of Hematology and Infectious Diseases. 2011;3(1). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103256/pdf/mjhid-3-e2011005.pdf>. Accessed April 16, 2018.

⁷⁷ Randa Hamadeh, Abbas Ardehali, Richard M. Locksley, Mary K. York. Fatal Aspergillosis Associated with Smoking Contaminated Marijuana, in A Marrow Transplant Recipient. Chest. 1988;94(2):432-433. <http://www.sciencedirect.com/science/article/pii/S0012369216334845>. Article must be purchased to be accessed.

⁷⁸ Charles Kaspar, M. Ellin Doyle, and John Archer. *White Paper on Non-O157:H7 Shiga Toxin-Producing E. coli from Meat and Non-Meat Sources*. Fri Food Safety Reviews. April 2010. Pages 2-4. Available at: https://fri.wisc.edu/files/Briefs_File/FRI_Brief_NonO157STEC_4_10.pdf. Accessed April 16, 2018.

⁷⁹ Roy Upton, Mahmoud ElSohly et.al. *Cannabis Inflorescence Cannabis spp. Standards of Identity, Analysis, and Quality Control*. Scott's Valley, CA: American Herbal Weia; 2013. Book must be purchased to be accessed.

⁸⁰ Washington Administrative Code. WAC 314-55-102. Chapter 214-55. Liquor and Cannabis Board. Marijuana Licenses, Application Process, Requirements, and Reporting. Quality Assurance Testing.

⁸¹ Cannabis Safety Institute. *Microbiological Safety Testing of Cannabis*. May 2015. Available at: <http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/Microbiological-Safety-Testing-of-Cannabis.pdf>. Accessed April 16, 2018.

gastrointestinal disease in both healthy as well as immunocompromised hosts.⁸² Because of the low infectious dose required for disease causation, there is zero tolerance for the presence of any *Salmonella* in all non-inhalable cannabis products. The appropriate action level has been decided that no *Salmonella* shall be detected in 1 gram, based on levels recommended by other states' regulations⁸³ and the Cannabis Safety Institute's report on microbiological safety testing.⁸⁴ This is necessary to establish the acceptance criteria for the sample to pass for *Salmonella* testing.

Proposed subsection (e) specifies that if the sample fails microbial impurities testing, the batch from which the sample was taken may not be released for retail sale. This is necessary to establish the action that must be taken with samples and related batches that fail microbial impurities testing.

§ 5721. Mycotoxin Testing.

Proposed section 5721 requires the testing laboratory to test all cannabis good samples for mycotoxins. Mycotoxins are toxic substances produced by fungal organisms that can grow on agricultural grains and produced food⁸⁵. Human exposure to mycotoxins includes ingestion, inhalation, and dermal contact.⁸⁶ It is necessary for the Bureau to establish the mycotoxins that must be tested for in each sample and establish corresponding action levels to ensure the cannabis goods can be consumed without harmful results on the patient's/consumer's health. The benefit of this section is that cannabis goods will be tested for harmful mycotoxins and any cannabis goods that do not pass testing will not be transported to retail and sold to consumers thereby protecting the health and safety of the consumer.

Proposed subsection (a) specifies that the testing laboratory must analyze 0.5 grams of the representative sample of cannabis goods to determine whether mycotoxins are present. This is necessary to ensure that the laboratory tests an appropriate amount of each sample for mycotoxins to obtain accurate results. Furthermore, this requirement is necessary because cannabis test methods are not standardized, but requiring the laboratories to use the same minimum amount of sample to analyze for mycotoxins will provide equilibrium in sample

⁸² Cannabis Safety Institute. *Microbiological Safety Testing of Cannabis*. May 2015. Available at: <http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/Microbiological-Safety-Testing-of-Cannabis.pdf>. Accessed April 16, 2018.

⁸³ Washington Administrative Code. WAC 314-55-102. Chapter 214-55. Liquor and Cannabis Board. Marijuana Licenses, Application Process, Requirements, and Reporting. Quality Assurance Testing.

⁸⁴ Cannabis Safety Institute. *Microbiological Safety Testing of Cannabis*. May 2015. Available at: <http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/Microbiological-Safety-Testing-of-Cannabis.pdf>. Accessed April 16, 2018.

⁸⁵ VICAM, Mycotoxin Testing Is Vital to the Future of the Medical Marijuana Industry <http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjcbt242PzSAhVE0mMKhbPoDuMQFggrMAA&url=http%3A%2F%2Fvicam.com%2FLiteratureRetrieve.aspx%3FID%3D229610&usg=AFQjCNHTt5S5_4t3-mefp5Ke8Aot83NmJQ> (as of Mar. 29, 2017).

⁸⁶ M. Peraica, B. Radic, A. Lucic & M. Pavlovic. Toxic effects of mycotoxins in humans. Bulletin of World Health Organization. 1999;77(9):754-766.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2557730/pdf/10534900.pdf>. Accessed April 16, 2018.

analysis between the various laboratories. During the first 6 months of the emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. There is a requirement for the laboratories to obtain a representative sample, mandating that a minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories.

After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories.

Proposed subsection (b) specifies that the testing laboratory shall indicate the results of the mycotoxin testing for a sample by clearly indicating the levels of mycotoxins found, if any, and by designating a pass or fail on that sample's certificate of analysis (COA). The laboratory must report the level of mycotoxins in the appropriate units and indicate if that value passes or fails the action level established in this section. This is necessary because it ensures the recipient(s) of the COA can easily identify the mycotoxin testing results for the sample and its associated batch.

Proposed subsection (c) enumerates the identity and action levels of mycotoxins that are required to be tested by the laboratory on all cannabis samples and cannabis product samples. The sample will pass mycotoxin testing if the levels are below 20 µg/kg (micrograms per kilogram) of substance. Action levels for mycotoxins proposed in these regulations are based on those established by the federal Food and Drug Administration⁸⁷ as well as on other states' commercial cannabis regulations.^{88,89} This is necessary to ensure that all cannabis goods are free of the specified mycotoxins or contain levels of these mycotoxins that will not adversely affect the health of the patients/consumers.

Proposed subsection (c)(1) requires that the total amount of specified aflatoxins does not exceed the action level of 20 µg/kg of substance. Aflatoxins are toxic substances produced by two major *Aspergillus* species: *A. flavus* and *A. parasiticus*. There are four main types of aflatoxins: B1, B2, G1, and G2. Aflatoxins are both acutely and chronically toxic in animals and humans. The disease primarily attacks the liver, causing necrosis, cirrhosis,

⁸⁷ Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. US Food and Drug Administration. Aug 2000.

<https://www.fda.gov/food/guidanceregulation/ucm077969.htm>. Accessed April 17, 2018.

⁸⁸ Nevada Administrative Code of Correctness. NAC 453A.658. Chapter 453A. Medical Use of Marijuana. Production and Distribution of Medical Marijuana. Requirements for Independent Testing Laboratories.

⁸⁹ Washington Administrative Code. WAC 314-55-102. Chapter 214-55. Liquor and Cannabis Board. Marijuana Licenses, Application Process, Requirements, and Reporting. Quality Assurance Testing.

and carcinomas. Many substrates support growth of aflatoxigenic molds and aflatoxin production. Natural contamination of cereals, figs, oil-seeds, nuts, tobacco, and other plant-based commodities is a common occurrence.⁹⁰ Because of the broad scope of agricultural products found to be contaminated with aflatoxins, the total amount of the four major aflatoxin types of B1, B2, G1, and G2 should not exceed the action level based on those established by the FDA.⁹¹ This proposal is necessary to establish the four major aflatoxin types that all cannabis goods shall be tested for and to establish the related action levels for these aflatoxins.

Proposed subsection (c)(2) requires that the total amount of Ochratoxin A does not exceed the action level of 20 µg/kg of substance. Ochratoxins are secondary metabolites of *Aspergillus* and *Penicillium* strains found on a variety of food commodities. The most toxic and frequently encountered of all ochratoxins is Ochratoxin A. Ochratoxin A has been shown to be nephrotoxic, immunosuppressive, carcinogenic, and teratogenic in all experimental animals tested thus far. Ochratoxin A has been found in barley, oats, rye, wheat, coffee beans, and other plant-based products.⁹² Because of its presence in a variety of agricultural plant products, the total amount of Ochratoxin A should not exceed the action level based on the levels for other mycotoxins established by the FDA.⁹³ This is necessary to establish the type of ochratoxin that all cannabis goods shall be tested for and to establish the related action level for this ochratoxins.

Proposed subsection (d) specifies that if the representative sample fails mycotoxin testing, the batch from which the sample was taken may not be released for retail sale. This is necessary to establish the action that must be taken with samples and related batches that fail mycotoxins testing.

§ 5722. Foreign Material Testing.

Proposed section 5722 requires the testing laboratory to test all cannabis good samples for foreign material. Foreign material can be introduced to cannabis or cannabis products by preharvest contamination, postharvest handling, or processing protocols. The amount of foreign material on the representative sample indicates how sanitary the corresponding batch may be. It is necessary for the Bureau to establish the different types of foreign materials that cannabis goods must be tested for and establish the corresponding action levels⁹⁴. The benefit of this section is that cannabis goods will be tested for harmful foreign

⁹⁰ Bennett JW and Klich M. Mycotoxins. *Clinical Microbiology Reviews*. 2003;16(3):497-516. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf>. Accessed April 17, 2018.

⁹¹ Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. US Food and Drug Administration. Aug 2000. <https://www.fda.gov/food/guidanceregulation/ucm077969.htm>. Accessed April 17, 2018.

⁹² Bennett JW and Klich M. Mycotoxins. *Clinical Microbiology Reviews*. 2003;16(3):497-516. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf>. Accessed April 17, 2018.

⁹³ Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. US Food and Drug Administration. Aug 2000. <https://www.fda.gov/food/guidanceregulation/ucm077969.htm>. Accessed April 17, 2018.

⁹⁴ U.S. Food and Drug Administration, *Macroanalytical Procedures Manual (MPM)* (Jun. 2015) <https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm083194.htm#sco_pe> (as of Mar. 29, 2017).

materials and any cannabis goods that do not pass testing will not be transported to retail and sold to consumers thereby protecting the health and safety of the consumer.

Proposed subsection (a) specifies that the testing laboratory must analyze the representative sample of cannabis goods to identify if foreign material is present. This is necessary to ensure that the laboratory tests each sample for foreign material.

Proposed subsection (b) specifies that the testing laboratory shall indicate the results of the foreign material testing for the sample by designating a pass or fail on that sample's COA. The laboratory must report whether or not any foreign material is present and exceeds the specified action levels established in this section. This is necessary to ensure the recipient(s) of the COA can easily identify the results from foreign material testing for the sample and its associated batch.

Proposed subsection (c) requires that the testing laboratory shall test for foreign material on the total representative sample before it is homogenized. Sample homogenization combines the sample so that it has the same composition throughout. Homogenization would prevent the testing laboratory from being able to distinguish if the presence of any foreign material exceeds the action levels set forth in this section. This is necessary to establish a timeline that the laboratory must follow for accurate results and to ensure that the testing laboratory does not examine the sample after homogenization.

Proposed subsection (d) enumerates the required actions that the testing laboratory shall include in the inspection of the total representative sample. This is necessary because it clarifies the actions that the testing laboratory must perform in order to correctly conduct the foreign material test.

Proposed subsection (d)(1) specifies that the testing laboratory must inspect the exterior and interior of the total dried flower sample. Because cannabis has characteristics that can allow foreign material to access the interior crevices of the flower, it is necessary to examine both the exterior and interior. This is necessary to ensure the testing laboratory can verify that the total representative sample does not exceed the action levels set forth in this section.

Proposed subsection (d)(2) specifies that the testing laboratory must inspect the exterior of the cannabis goods sample. Because cannabis products have been processed in a manner that the interior of the product is not accessible by foreign material, it is necessary to examine only the exterior. This is necessary to ensure the testing laboratory can verify that the total representative sample does not exceed the action levels set forth in this section.

Proposed subsection (e) enumerates the action levels for different foreign materials. Because there is a lack of official studies about foreign material in cannabis goods, it is necessary to reference the US Food and Drug Administration's *Defect Levels Handbook—The Food Defect Action Levels*.⁹⁵ This is necessary to establish the action levels for the different foreign materials that can contaminate cannabis goods.

⁹⁵ US Food and Drug Administration, Defect Levels Handbook: The Food Defect Action Levels, February 2005

Proposed subsection (e)(1) specifies that the testing laboratory shall not pass the cannabis goods sample if more than one fourth of the total area is covered by sand, soil, cinders, or dirt. The action level of one fourth the total area is based on the FDA's levels for such contaminants in agricultural produce and plant-based products.⁹⁶ This is necessary to establish action levels that the laboratory must use when examining the sample for foreign material.

Proposed subsection (e)(2) specifies that the testing laboratory shall not pass the cannabis goods sample if more than one fourth of the total area is covered by mold. This is evidenced by the presence of mold hyphae and/or spore forming structures that are visible macroscopically and microscopically. The action level of one fourth the total area is based on the FDA's mold levels for agricultural produce and plant-based products.⁹⁷ This is necessary to establish action levels that the laboratory must use when examining the sample for foreign material.

Proposed subsection (e)(3) specifies that the testing laboratory shall not pass the cannabis goods if more than one insect fragment, one hair, or one count of mammalian excreta is found per three grams of sample. Any living or dead insect present at any life cycle stage, or evidence of their presence, shall be taken into consideration. The action levels proposed are based on the FDA's levels for insect and rodent contaminants in agricultural produce and plant-based products.⁹⁸ This is necessary to establish action levels that the laboratory must use when examining the sample for foreign material.

Proposed subsection (e)(4) specifies that the testing laboratory shall not pass the cannabis or cannabis product if more than one fourth of the total area is covered by an imbedded foreign material. Any foreign matter imbedded in the cannabis or cannabis product sample associated with objectionable conditions in production, storage, or distribution shall be taken into consideration. The action level of one fourth the total area is based on the FDA's foreign matter levels for certain plant-based products.⁹⁹ This is necessary to establish action levels that the laboratory must use when examining the sample for foreign material.

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm>. Accessed April 17, 2018.

⁹⁶ US Food and Drug Administration, Defect Levels Handbook: The Food Defect Action Levels, February 2005

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm>. Accessed April 17, 2018.

⁹⁷ US Food and Drug Administration, Defect Levels Handbook: The Food Defect Action Levels, February 2005

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm>. Accessed April 17, 2018.

⁹⁸ US Food and Drug Administration, Defect Levels Handbook: The Food Defect Action Levels, February 2005

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm>. Accessed April 17, 2018.

⁹⁹ US Food and Drug Administration, Defect Levels Handbook: The Food Defect Action Levels, February 2005

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm>. Accessed April 17, 2018.

Proposed subsection (f) specifies that if the sample fails foreign material testing, the batch from which the sample was taken may not be released for retail sale. This proposal is necessary to establish the action that must be taken with samples and related batches that fail foreign material testing.

§ 5723. Heavy Metals Testing

Section 5723 proposes the heavy metals that should be tested for and at what action levels the sample will be deemed to have failed heavy metal testing. The heavy metals listed are widely distributed in the global environment in soil, water, and fertilizer^{100,101}. Cannabis plants are known to pull up and accumulate these metals from the contaminated environment¹⁰². Therefore, it is important to test each cannabis sample for these elements to protect public health and reduce the potential risk of adverse health effects associated with the consumption of medicinal cannabis goods. These action levels have been established to protect the health of consumers of cannabis goods and reduce the risk of adverse health effects¹⁰³. Action levels were established in units of micrograms per gram of substance ($\mu\text{g/g}$). The benefit of this section is that cannabis goods will be tested for harmful heavy metals and any cannabis goods that do not pass testing will not be transported to retail and sold to consumers thereby protecting the health and safety of the consumer.

Proposed subsection (a) specifies that the laboratory must test a minimum of 0.5 grams of the cannabis goods representative sample. Heavy metal testing is one of the required analyses to determine potential impurities in cannabis goods. This is necessary to ensure the laboratory tests an appropriate amount of each sample for heavy metals. Furthermore, this requirement is necessary because cannabis test methods are not standardized, but requiring the laboratories to use the same minimum amount of sample to analyze for heavy metals will provide equilibrium in sample analysis between the various laboratories. During the first 6 months of the emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. There is a requirement for the laboratories to obtain a representative sample, mandating that a

¹⁰⁰ Office of Environmental Health Hazard Assessment (OEHHA), Air Toxics Hot Spots Program, *Guidance Manual for Preparation of Health Risk Assessments*. (Feb. 2015) State of California, Appendices 6-10

<<https://oehha.ca.gov/media/downloads/crnr/2015guidancemanual.pdf>> Accessed October 5, 2017.

¹⁰¹ 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 Jun. 7, 2018)

¹⁰² Tangahu, B.V., et al., *A review on heavy metals (As, Pb, and Hg) uptake by plants through phytoremediation* (2011) International Journal of Chemical Engineering, Volume 2011, Article ID 939161 <<http://dx.doi.org/10.1155/2011/939161>> (as of Mar. 28, 2017).

¹⁰³ U.S. Food and Drug Administration (FDA), *FDA's Testing of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content* (Dec. 2016) <<http://www.fda.gov/cosmetics/productsingredients/potentialcontaminants/ucm452836.htm>> (as of Mar. 28, 2017).

minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories.

After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories.

Proposed subsection (b) specifies that the laboratory must report the heavy metal test result in $\mu\text{g/g}$ (micrograms per gram) unit on the certificate of analysis (COA). In addition, this provision specifies that the laboratory must report the test results for heavy metals detected in a cannabis and cannabis sample on the COA and indicate “pass” or “fail”. This provision is necessary to create uniformity and consistency in reporting. Uniform and consistent reporting is necessary to enable both the Bureau and licensees to objectively compare analytical reports. This ensures that the entity that requested the analytics be provided accurate and complete information about the samples tested.

Proposed subsection (c) specifies that a laboratory must report that a sample passes testing for the heavy metals cadmium (Cd), lead (Pb), arsenic (As) and mercury (Hg) only if the concentration of heavy metals does not exceed the action levels listed. These elements are all listed as Class 1 elemental impurities in drug products by the US Food and Drug Administration.¹⁰⁴ Testing for these four heavy metals is necessary because they are human toxicants that have limited or no useful biological function in human organisms. Cadmium (Cd) and arsenic (As) are both known to be genotoxic and are human carcinogens.

Exposure to lead (Pb) may cause neurological, reproductive, developmental, immune, cardiovascular, and renal health effects¹⁰⁵. Mercury (Hg) shows toxicological effects including neurological, corrosive, hematopoietic, and renal effects and cutaneous disease (acrodynia). The action levels for these four heavy metals have been established on the basis of safety data for oral and inhalation consumption and are recommended by the US Food and Drug Administration.

¹⁰⁴ *Q3D Elemental Impurities Guidance for Industry*. Food and Drug Administration (FDA), 2015. <https://www.fda.gov/downloads/drugs/guidances/ucm371025.pdf>. Accessed May 16, 2018.

¹⁰⁵ U.S. Food and Drug Administration, *Draft Guidance for Industry: Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level* (2016) <<https://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm452623.htm>> (as of Mar. 28, 2017).

| Heavy Metal | Action Level ($\mu\text{g/g}$) | |
|--------------------|--|-----------------------------|
| | Inhalable Cannabis Goods | Other Cannabis Goods |
| Cadmium | 0.2 | 0.5 |
| Lead | 0.5 | 0.5 |
| Arsenic | 0.2 | 1.5 |
| Mercury | 0.1 | 3.0 |

Proposed subsection (d) specifies that if the sample fails the heavy metal test, the batch from which the sample was taken may not be released or sold for retail sale. Every failed batch must be returned to the requester and should be held until further action.

§ 5724. Cannabinoid Testing

Proposed section 5724 provides the requirements for the laboratory testing of cannabis goods samples to determine whether the cannabinoid profile of the sample conforms to the labeled content of each cannabinoid. This section also specifies the manner in which the laboratory must calculate and report, on the COA, the content of cannabinoids detected in the sample^{106,107,108}. Business and Professions Code section 26100(d)(1) requires testing of specific cannabinoids including THC¹⁰⁹, THCA, CBD, CBDA, CBG, and CBGN, unless limited through regulation by the Bureau. The Bureau has determined that, in the interest of public safety, that the laboratory should be required to test for any cannabinoid for which there is a label claiming the presence of such cannabinoid in the cannabis goods being sampled. The benefit of this section is that the labeled cannabinoids on cannabis goods will be verified through laboratory testing so that no products that do not meet requirements set by the Department of Public Health for THC limits will be transported to retail and sold to consumers. The other benefit is that consumers will be aware of the amount of cannabinoids in each product and therefore able to determine how much of the product they should consume at one time based on their individual tolerance level.

¹⁰⁶Grotenhermen F., Pharmacokinetics and pharmacodynamics of cannabinoids (2003) Clin. Pharmacokinet., 42(4):327-60 <<https://www.ncbi.nlm.nih.gov/pubmed/12648025>> (as of Mar. 29, 2017).

¹⁰⁷ Thomas B.F., et al. *Analytical Chemistry of Cannabis: Quality Assessment, Assurance, and Regulation of Medical Marijuana and Cannabinoid Preparations*. (2016) Waltham, MA: Elsevier.

¹⁰⁸ Trofin G.I., et al., The Influence of Long-Term Storage Conditions on the Stability of Cannabinoids Derived from Cannabis Resin (2012) Revista de Chimie (Bucharest), 63(4):422-427.

¹⁰⁹ Karschner, E., et al., Plasma Cannabinoid Pharmacokinetics Following Controlled Oral Δ9-Tetrahydrocannabinol and Oromucosal Cannabis Extract Administration. (2011) Clin Chem., 57(1): 66–75

Proposed subsection (a) requires the laboratory to analyze at least 0.5 grams of the representative sample of a cannabis good batch to determine whether the cannabinoid profile of the sample conforms to the labeled content of cannabinoids such as THC; THCA; CBD; CBDA; CBG; and CBN.^{110,111} This is necessary to ensure the laboratory tests an appropriate amount of each sample for cannabinoids. Furthermore, this requirement is necessary because cannabis test methods are not standardized, but requiring the laboratories to use the same minimum amount of sample to analyze for cannabinoids will provide equilibrium in sample analysis between the various laboratories. During the first 6 months of the emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. There is a requirement for the laboratories to obtain a representative sample, mandating that a minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories.

After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories.

Proposed subsection (b) requires the laboratory to report, on the COA, the result of the cannabinoid testing as a percentage and in milligrams per gram (mg/g), if by dry-weight, or milligrams per milliliter (mg/ml), if by volume, whichever is more appropriate based on the type of cannabis goods. This is necessary to ensure that all testing laboratories report results in the same manner, using the same units of measurement.

This proposed subsection also requires the laboratory to verify that the cannabis goods label conforms with the cannabinoid profile test results and indicate “pass” or “fail” on the COA. This is necessary to ensure that all testing laboratories report results in the same manner and to clearly inform the requester of the results of the testing. It is also necessary to require that labs include a pass or fail for the label claim verification on the COA so that it is clear to the distributor whether a sample has or has not passed compliance testing.

¹¹⁰Butterfield, D. 10 Strongest Dabs You Can Buy Right Now (Aug. 31, 2016) Herb <<http://herb.co/2016/08/31/strongest-dabs/>> (as of Oct. 4, 2017).

¹¹¹ 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 Jun. 7, 2018)

This determines whether or not the cannabis goods batch can be moved to a licensed retailer. This will also ensure consistent reporting on the certificate of analysis.

Proposed subsection (b)(1) requires that the dry-weight percentage of the cannabinoids listed in proposed subsection (a) should be reported in the certificate of analysis and how it should be calculated. The calculation formula is based on [$CD = CW / Ps \times 100$],¹¹² where CD is concentration corrected for dry weight; CW is wet-weight concentration; and Ps is percent solid. This equation is mathematically equivalent as [$Ps = 1 - \text{percent moisture}$] to remove the portion of moisture from cannabis^{113,114}. This is necessary to ensure all laboratory results are reported in the same manner, using the same equation. Furthermore, correcting for moisture and reporting dry-weight percent reveals the actual concentration of the cannabinoids in the solids of the cannabis goods. Reporting wet-weight concentration for solid cannabis goods may lead to differing measurements due to the amount of moisture in that particular product. Therefore, moisture correction (that is, calculating and reporting in dry-weight concentration) is necessary to ensure consumers may compare cannabinoid concentrations in cannabis that have varying moisture contents. This requirement would allow consumers to know that they are directly comparing the potency of different batches, regardless of the moisture make-up of those products. The federal Environmental Protection Agency requires dry-weight correction under some analytical protocols, and the Department of Defense requires reporting on a dry-weight basis for their contract laboratories.

Proposed subsection (c) requires that if the labeled content of any one cannabinoid is expressed as a total concentration of the cannabinoid, the laboratory shall calculate the total cannabinoid concentration using specific equations:

(1) For concentration expressed in weight:

Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g)

(2) For concentration expressed in volume:

Total cannabinoid concentration (mg/mL) = (cannabinoid acid form concentration (mg/mL) x 0.877) + cannabinoid concentration (mg/mL)

¹¹² Environmental Chemistry Consulting Services, Ask the Chemist Vol. 2 - Dry Weight vs. Wet Weight Results, 2011, <http://www.eccsmobilelab.com/resources/literature/?Id=117>. Accessed March 28, 2017.

¹¹³ digipathLabs, Moisture Residue Analysis (2015) <<http://digipathlabs.com/moisture-residue-analysis/>> (as of Mar. 28, 2017).

¹¹⁴ Analytical 360, Moisture Analysis <<http://analytical360.com/cannabis-analysis-laboratory/interpreting-your-laboratory-data>, 2015> (as of Mar. 28, 2017).

This requirement is necessary to ensure all testing laboratories are calculating total cannabinoid concentration in the same manner.

Proposed subsection (d) enumerates the acceptance criteria for cannabinoid label claims. It describes that a laboratory must report that a sample passes testing for cannabinoid content, if a cannabinoid claimed to be present at 5% or greater of the total cannabinoid profile, does not exceed the labeled content. It also clarifies that batches which fail cannabinoid testing, may not be released for retail sale. This is necessary to provide guidance and clarity to the regulated public. The California Department of Public Health (CDPH) was consulted, and together with the BCC, it was determined a tiered approach to allow for a greater variance was necessary to address micro-dosed products.

In the first 6 months of regulatory implementation, non-reproducibility was displayed when QA test results determined what the producer should label the product with, but even if the same laboratory performed the regulatory compliance testing, the product failed because the same laboratory was unable to reproduce their results. It is unnecessary to fail a product containing a meniscal amount of a cannabinoid, as there is no significant public health safety concern, because such small amounts of cannabinoids have little or no effect physically on the consumer.

It was determined that cannabis goods containing less than 5% of a specific cannabinoid content would not need label verification, because the amount of cannabinoid present could not be consistently or accurately be tested. Furthermore, the reproducibility of such small amounts of a specific cannabinoid would not be achieved between the various testing laboratories. Reproducibility could not be achieved, not because of varying test methods, but because laboratories are not able to reproduce such meniscal amounts of cannabinoids within +/- 10% of the label claim.

Proposed subsection (d)(1) to (d)(3) enumerates a tiered approach to the cannabinoid acceptance criteria based on how many mg per serving are present in edible cannabis products. This is necessary because it is unrealistic for edible cannabis products that contain very small amounts of cannabinoids, to be within plus or minus 10% of that label claim. Furthermore, a tiered approach allows edibles less than 5 mg, and also those less than 2 mg to have a larger acceptance criteria window. For example, low dosed or micro-dosed cannabis goods containing smaller amounts, 2 mg of THC pose less of a safety hazard due to the lower dose. As a result, the tolerance ranges should be adjusted to take this in to account.

Proposed subsection (d)(1) requires edible cannabis products with a cannabinoid serving size greater than 5.1 mg, and requires all other cannabis goods, the concentration of any one cannabinoid shall not exceed the labeled content of that cannabinoid, plus or minus 10%. A tolerance of plus or minus 10% variance protects consumers while allowing for

variation in manufacturing processes¹¹⁵. Proper labeling is critical to ensuring that cannabis users are sufficiently informed of product potency and can make informed decisions when purchasing cannabis goods. Requiring cannabis goods to be within plus or minus 10% of their labeled content is not an unreasonable variance.

requires edible cannabis products with a cannabinoid serving size greater than 5.1 mg, and for all cannabis goods, the concentration of any one cannabinoid shall not exceed the labeled content of the cannabinoid, plus or minus 10%.

Proposed section (d)(2) requires edible cannabis products with a cannabinoid serving size of 2.1 mg to 5.0 mg, the concentration of any one cannabinoid shall not exceed the labeled content of the cannabinoid, plus or minus 15%. A variance of 15% was determined to be an appropriate percentage based on the laboratories reproducibility and based on the product containing a lower smaller amount of cannabinoids.

For example, edible products labeled at 4.0 mg of THC per serving will pass cannabinoid testing if the laboratory measures a result between 3.4 mg and 4.6 mg of THC per serving. The difference of 0.6 mg should not cause an edible production batch to fail. It is unnecessary to fail a product containing a meniscal amount of a cannabinoid, as there is no significant public health safety concern, because such small amounts of cannabinoids have little or no effect physically on the consumer.

Proposed section (d)(3) requires edible cannabis products with a cannabinoid serving size of less than or equal to 2.0 mg, the concentration of any one cannabinoid shall not exceed the labeled content of the cannabinoid, plus or minus 25%. A variance of 25% was determined to be an appropriate percentage based on the laboratories reproducibility and based on the product containing such meniscal amounts of cannabinoids.

For example, edible products labeled at 2.0 mg of THC per serving will pass cannabinoid testing if the laboratory measures a result between 1.5 mg and 2.5 mg of THC per serving. The difference of 0.5 mg should not cause an edible production batch to fail. It is unnecessary to fail a product containing a meniscal amount of a cannabinoid, as there is no significant public health safety concern, because such small amounts of cannabinoids have little or no effect physically on the consumer.

Proposed subsection (e) specifies that if the sample fails cannabinoid testing, the batch from which the sample was taken may not be released for retail sale. This is necessary to ensure that no cannabis goods are sold pursuant to a license if the chemical profile of the

¹¹⁵ Center for Drug Evaluation and Research (CDER), U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment (Oct. 2003) Pharmaceutical Current Good Manufacturing Practices (CGMP)
<<https://www.fda.gov/ohrms/dockets/98fr/03d-0493-gdl0001.doc>> (as of Mar. 30, 2017).

sample does not conform to the labeled content of the compound. This is a requirement under Business and Professions Code section 26100(d)(1).

§ 5725. Terpenoid Testing

Proposed section 5725 provides the requirements for the laboratory testing of cannabis goods samples to determine whether the terpenoid profile of the sample conforms to the labeled content of terpenes. Business and Professions Code section 26100(d)(1)(E) requires testing of the terpenes required by the Bureau in regulation. The Bureau has determined that, in the interest of public safety, that the laboratory should be required to test for any terpenoid for which there is a label claiming the presence of such terpenoid in the cannabis good being sampled.

Proposed subsection (a) clarifies the language in Business and Professions Code section 26100 about when and how the laboratory shall test and report the terpenes in the sample that are listed on the label of the batch. Terpenes are generally recognized as safe and as having no adverse health effects to human beings.¹¹⁶ Therefore, the Bureau recommends adopting this provision to permit optional testing for terpenoids. The reason for this subsection is to ensure consistency between the product and the labeling.

This subsection requires that the laboratory shall analyze a minimum of 0.5 grams of the representative sample of cannabis goods to determine whether the terpenoid profile of the sample conforms to the labeled content. This is necessary to ensure the laboratory tests an appropriate amount of each sample for terpenoids. Furthermore, this requirement is necessary because cannabis test methods are not standardized, but requiring the laboratories to use the same minimum amount of sample to analyze for terpenoid will provide equilibrium in sample analysis between the various laboratories. During the first 6 months of the emergency regulation implementation, BCC technical staff reviewing the various laboratories SOPs, noticed a vast difference in the amount of sample used for testing. For example, the variance ranged from 0.05 grams to 1.0 grams. There is a requirement for the laboratories to obtain a representative sample, mandating that a minimum amount of sample is used in the various analyses, helps the laboratories achieve symmetry – the amount of sample prepared will be the same, thus moving the industry toward standardized sample preparation and ultimately standardized testing. Standardized testing would reduce variance in test results between the laboratories.

After sample homogenization, the laboratories aliquot smaller portions for the various tests or a small more manageable portion is selected for analysis - ideally it will have properties which are representative of the batch from which it was originally selected. Laboratories

¹¹⁶ EB Russo, Taming THC: potential cannabis synergy and phytocannabinoid-terpenoid entourage effects, British Journal of Pharmacology (2011), 163, 1344-1364.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3165946/>. Accessed March 28, 2017.

will naturally reduce the size of the representative sample for analysis, but in order to obtain reliable and repeatable results it is necessary to require a minimum amount of sample to be tested. Moving toward standardized testing will help eliminate the variance in results across the licensed testing laboratories.

Proposed subsection (b) requires the laboratory to report the result of the terpenoid testing on the COA both as a percentage and in either milligrams per gram (mg/g) if by weight or milligrams per milliliter if by volume. This is necessary to ensure that all the labs report results in the manner, using the same units of measurement.

This proposed subsection also requires the laboratory to verify that the cannabis goods label conforms with the terpenoid profile test results and indicate “pass” or “fail” on the COA. This is necessary to ensure that all the labs report results in the manner and to clearly inform the requester of the results of the testing. It is also necessary to require that labs include a pass or fail for the label claim verification on the COA so that it is clear to the distributor whether a sample has or has not passed compliance testing. This determines whether or not the cannabis goods batch can be moved to a licensed retailer. This will also ensure consistent reporting on the certificate of analysis.

Proposed subsection (c) requires the sample shall be deemed to have passed the terpenoid testing if the concentration of any one terpenoid, claimed to be present at 5% or greater of the total terpenoid profile, does not exceed the labeled content of the terpenoid, plus or minus 10%. This is necessary to provide guidance and clarity to the regulated public. A tolerance of plus or minus 10% variance protects consumers while allowing for variation in manufacturing processes. Proper labeling is critical to ensuring that cannabis users are sufficiently informed of product potency and can make informed decisions when purchasing cannabis products. Requiring cannabis goods to be within plus or minus 10% of their labeled content is not an unreasonable variance.

It was determined that cannabis goods containing less than 5% of a specific terpenoid content would not need label verification, because the amount of terpenoid present could not be consistently or accurately be tested. Furthermore, the reproducibility of such small amounts of a specific terpenoid would not be achieved between the various testing laboratories. Reproducibility could not be achieved, not because of varying test methods, but because laboratories are not able to reproduce such meniscal amounts of terpenoids within +/- 10% of the label claim.

For example, in the first 6 months of regulatory implementation, non-reproducibility was displayed when QA test results determined what the producer should label the product with, but even if the same laboratory performed the regulatory compliance testing, the product failed because the same laboratory was unable to reproduce their results. It is unnecessary to fail a product containing a meniscal amount of a terpenoid, as there is no

significant public health safety concern, because such small amounts of terpenoids have little or no effect physically on the consumer.

Proposed subsection (d) specifies that if the sample fails terpenoid testing, the batch from which the sample was taken may not be released for retail sale. This is necessary to ensure that no cannabis goods are sold at retail if the chemical profile of the sample does not conform to the labeled content of the compound. This is also a requirement under Business and Professions Code section 26100(d)(1).

§ 5726. Certificate of Analysis (COA)

Proposed section 5726 specifies the required information that the testing laboratory must include in the certificate of analysis (COA) for each representative sample analyzed. COAs are meant to report the results from each analysis performed on the sample and will be used by the distributor, retailer, and licensing authorities to verify the sample and its associated batch have passed all regulatory compliance testing. The section is necessary to systematically standardize COAs to include results and critical information that allows the Bureau and the public to trace the integrity of the testing results. The benefit is that COAS will be standardized and the Bureau will be able to trace the integrity of the testing results.

Proposed subsection (a) requires the testing laboratory to generate a COA for each representative sample that the laboratory analyzes. It is important that the results be reported for each sample individually. This is necessary to ensure the testing laboratory reports results for each sample by creating a COA for each sample.

Proposed subsection (b) requires the testing laboratory to certify the COA contains the results of all required analyses performed for the representative sample. The COA will act as the report with results from all the analyses performed on the sample and should include results for the tests that have been required by the Bureau on the sample. This is necessary to ensure the testing laboratory generates a COA that has the results from each required analysis.

Proposed subsection (c) requires the testing laboratory to upload the COA into the track and trace system and submit a copy of the COA to the Bureau via email, and any other requestors, within one business day of completing analyses of the sample. This is necessary to prevent delays in reporting results to the Bureau and will deter the diversion of failed batches from the legal market.

Proposed subsection (d) enumerates the required information that the COA must contain, at a minimum. This is necessary to inform the testing laboratory what they must include in a complete COA for each representative sample.

Proposed subsection (d)(1) specifies that the COA include the name, physical address, and license number of the testing laboratory that performed the analytical testing procedures. This is necessary to identify the laboratory responsible for sampling and testing while

enabling the Bureau to trace the integrity of the data and to hold the laboratory accountable for testing.

Proposed subsection (d)(2) specifies that the COA include the name, physical address, and license number of the distributor or microbusiness from which the sample was obtained. This is necessary to identify the source of the representative sample while enabling the Bureau to trace the location of the associated batch before its release to retail.

Proposed subsection (d)(3) specifies that the COA include the name, physical address, and license number of the cultivator, manufacturer, or microbusiness from which the sample was obtained. This is necessary to identify the source of the representative sample's associated batch and.

Proposed subsection (d)(4) specifies that the COA include the batch number of the batch from which the sample was obtained. This is necessary because the ability to trace back to batches will enable the Bureau to efficiently and quickly halt the distribution of cannabis goods batches that do not pass the required analyses.

Proposed subsection (d)(5) specifies that the COA include identifying information of the sample, including matrix type, such as dried flower, oil, resin, etc. and any unique sample identifiers that will help to distinguish individual samples. This information is necessary to identify the composition of the samples and to verify that the correct methods were used for analyses of the sample while ensuring the correct results are paired with the correct unique sample identifiers.

Proposed subsection (d)(6) specifies that the COA include the sample history, including the dates the sample was collected, received by the laboratory, and analyzed. This is necessary to establish a timeline of the sample's history which will enable the Bureau to identify potential problems related to the sampling, transfer, or analyses.

Proposed subsection (d)(7) specifies that the COA include a picture of the cannabis goods, including any applicable packaging. This is necessary because a picture of the sample will help the recipient(s) of the COA determine which cannabis goods the results are for and will help the Bureau determine if the correct analyses and results were reported for the sample.

Proposed subsection (d)(8) specifies that the COA include the total weight of the dried flower sample in grams or pounds and the total weight of the representative cannabis sample in grams. This is necessary to determine the validity of the batch based on its maximum weight and to verify that the correct increment of samples and amount of material was collected.

Proposed subsection (d)(9) specifies that the COA include the total unit count of the cannabis goods product and the total unit count of the representative cannabis product sample. This is necessary to determine the validity of the batch based on its maximum unit count and to verify that the correct increment of samples was collected.

Proposed subsection (d)(10) specifies that the COA include the measured density of the cannabis goods. Density is an integral part of determining the total concentration of cannabinoid and terpenoid levels in certain products. This is necessary to ensure

calculations performed by the testing laboratory are accurate when reporting the test results for cannabinoids and terpenoids.

Proposed subsection (d)(11) specifies that the COA include the analytical methods and instrumentation used with the corresponding limits of detection (LOD) and limits of quantitation (LOQ). This is necessary to ensure the testing laboratory is performing testing using the appropriate methods that have been submitted to the Bureau and ISO/IEC 17025 accredited while ensuring the levels that the laboratory can test for are within regulation.

Proposed subsection (d)(12) specifies that the COA include an attestation that all laboratory quality control (LQC) samples were performed and met the acceptance criteria. An attestation will allow the laboratory to release a COA without detailing the LQC sample results, but will hold the laboratory responsible for the LQC samples. This is necessary to ensure the testing laboratory performs the required quality control procedures when analyzing samples and to hold the laboratory responsible in the event that LQC samples were not performed or did not meet the acceptance criteria.

Proposed subsection (d)(13) specifies that the COA include any analytes that were detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed. Testing laboratories may test for other analytes in addition to the ones required by the Bureau. This is necessary to ensure that laboratories report any findings of analytes that could potentially cause harm to the consumer.

Proposed subsection (e) enumerates the requirements that the testing laboratory shall follow when reporting test results on the COA for each representative sample. This is necessary to establish a standardized reporting style that each laboratory can use to help convey results while enabling the recipient(s) of the COA to easily identify the results of the sample and its associate batch.

Proposed subsection (e)(1) requires the laboratory to indicate and report, on the COA, an overall “pass” or “fail” for the sample and its associated batch. An overall pass/fail will indicate if the representative sample has passed all required analyses. If the sample fails any of the required analyses, it will be deemed an overall fail. This is necessary to allow the recipient(s) of the COA to easily identify if a sample and its associated batch have passed all regulatory compliance testing.

Proposed subsection (e)(2) requires the laboratory to report, on the COA, qualitative results for each analyte by a “pass” or “fail” indication. Test methods that yield qualitative results shall be reported on the COA with a pass/fail indication for the sample. This is necessary to standardize how qualitative results are reported on the COA.

Proposed subsection (e)(3) requires the laboratory to report, on the COA, quantitative results for each analyte using the appropriate units of measurements. Test methods that yield quantitative results shall be reported following the appropriate units of measurement, such as cannabinoids being reported in a mg/g (milligram per gram) format for cannabis flower. This is necessary to standardize the units of measurement when quantitative results are reported on the COA and to ensure the laboratory is measuring analytes in the appropriate manner.

Proposed subsection (e)(4) requires the laboratory to indicate, on the COA, “pass” or “fail” when reporting results for each test method. A pass/fail indication for each test method will indicate provide specific information on the analyses of the sample. This is necessary to allow the recipient(s) of the COA to easily identify which analyses the sample has passed/failed.

Proposed subsection (e)(5) requires the laboratory to report, on the COA, any cannabinoid and/or terpenoid label claims if the cannabis or cannabis product sample has such claims. Cannabis goods that are packaged will more than likely have a label claim for the cannabinoid and/or terpenoid content. This is necessary to document the original claim that was made by the producer for the cannabis goods’ cannabinoid and/or terpenoid levels.

Proposed subsection (e)(5)(A) requires the laboratory to report, on the COA, the label claim from the sample on the COA. The label claim is typically the claim found on the cannabis goods sample’s packaging that describes the potency of the cannabinoids and/or terpenoids with a numerical value. This is necessary because the COA should document all related information from the sample, including the cannabinoid or terpenoid claim that the cannabis goods has.

Proposed subsection (e)(5)(B) requires the laboratory to report, on the COA, the test result, or actual value, for cannabinoid or terpenoids. This is necessary because it allows the recipient(s) of the COA to easily identify the true value of any cannabinoid or terpenoid levels in the sample and its associated batch.

Proposed subsection (e)(5)(C) requires the laboratory to report, on the COA, the difference, in percent, between the actual label claim and the laboratory test results, if applicable. If the test result for cannabinoid or terpenoid potency is shown to be different than the label claim for a cannabis or cannabis product sample, the laboratory shall indicate the difference between the two values. This is necessary to allow the recipient(s) of the COA to easily identify if a sample and its associated batch passed cannabinoid and/or terpenoid testing and the difference between the label claim and the actual value of any cannabinoid or terpenoid that may be in the sample.

Proposed subsection (e)(6) requires the laboratory to report, on the COA, results for analytes that were detected below the analytical method LOQ by indicating “<LOQ”. This is necessary to allow the recipient(s) of the COA to easily identify if the sample and its associated batch contain trace amounts of an analyte.

Proposed subsection (e)(7) requires the laboratory to report, on the COA, results for any analytes that were not detected, or that were detected below the LOD, by indicating “ND”. This is necessary to allow the recipient(s) of the COA to easily identify if the sample and its associate batch are clean from any contaminants that may be harmful.

Proposed subsection (e)(8) requires the laboratory to indicate, on the COA, “NT” for any test that the laboratory did not perform on the representative sample. This is necessary to allow the recipient(s) of the COA to easily identify if the sample and its associated batch have not had the appropriate analyses performed.

Proposed subsection (f) requires the laboratory supervisory or management employee to validate the accuracy of the information and results contained on the COA by signing and

dating the COA. This is necessary to ensure the laboratory supervisor or management employee evaluates the results included in the data package and confirms they are accurate while also being responsible for the validity of the laboratory's test results.

§ 5727. Remediation and Retesting

Proposed section 5727 describes the allowable procedures pertaining to remediation and retesting. Remediation is the process of resolving a quantified problem with a cannabis item that was the cause of the cannabis item to fail laboratory testing. Generally, remediation means the removal of a known contaminant from a specified item, in this case cannabis goods. In this context, however, remediation also means re-labeling of a cannabis goods package so that the labeled cannabinoid or terpenoid profile conforms with the actual cannabinoid or terpenoid profile of the package contents. The benefit of this section is that it provides a mechanism for cannabis goods that do not pass testing to be remediated where possible. Without the ability to remediate cannabis goods that fail testing, licensees would have to destroy the cannabis goods resulting in a loss of revenue.

Proposed subsection (a) requires a cannabis goods batch that has been additionally processed after failed testing must be retested and successfully pass all the analyses required under this chapter. This is necessary to provide guidance and clarity to the regulated public. The Bureau was intentional in not prescribing a remediation technique for each type of contamination issue. This was done, in part, because the science in this area is limited. Also, methods are being developed for remediation of specific pesticides and the Bureau wanted to leave room for technological innovation. In addition, there are numerous remediation processes for each type of contamination problem.

This proposed subsection also specifies that edible cannabis products may not be remediated after a failed testing. This is necessary because remediation of edible products is prohibited pursuant to the Department of Public Health's regulations promulgated under the MAUCRSA.

Proposed subsection (b) requires a cannabis goods batch that only failed testing because of nonconformance with the labeled content may be relabeled so that the batch conforms with the labeled content. Retesting is not required if the relabeling is performed at the distributor premises. This is necessary to provide clarity that re-testing is not required for a batch that has only failed for label claim. The appropriate way to remediate such a failed batch is to simply relabel.

Proposed subsection (c) requires the distributor or microbusiness to arrange for remediation of a failed harvest batch or cannabis product batch. If the batch cannot be remediated, the batch shall be destroyed. This is necessary to prevent diversion of a failed batch. Returning a failed batch without an arrangement for remediation prior to it leaving the distributor premises could result in the batch being diverted. Furthermore, pursuant section 5306, if a failed batch cannot be remediated, the batch shall be destroyed in the distributor premises.

Proposed subsection (d) requires that if a batch is not remediated or reprocessed in any way it cannot be retested. Any subsequent COAs produced without remediation or reprocessing of the failed batch will not supersede the initial regulatory compliance testing COA. This is

necessary to prevent lab-shopping. Lab-shopping can be described as one testing at multiple laboratories to obtain the most desirable result.

Proposed subsection (e) requires that a cannabis goods batch may only be remediated twice. If the batch fails after the second remediation attempt and the second retesting, the entire batch shall be destroyed. This is necessary to provide guidance and clarity to the regulated public. Concerning the limitation on the number of remediation attempts, the Bureau determined that a limit of twice is necessary to deter diversion of cannabis items to the illicit market

Proposed subsection (f) requires that within 1 business day of completing the required analyses of a representative sample obtained from a remediated cannabis goods batch, the laboratory shall upload the COA information into the track and trace system. This is necessary to track the results of the remediated batch.

§ 5728. Post Testing Sample Retention

Proposed section 5728 specifies the responsibility of the testing laboratory to hold any portion of the collected sample that was not used during the testing process, referred to as the reserve sample, in a manner that upholds sample integrity for a definite timeframe. It is important to hold the reserve sample, as it will be examined and retested in instances of data uncertainty, analysis errors, product recalls, or other occurrences of compliance issues. This section is necessary to ensure that the cannabis testing laboratory holds the reserve sample for the specified timeframe in a manner that will allow for the possibility of retesting the reserve sample, if needed.

Proposed subsection (a) specifies that the testing laboratory must keep the reserve sample for a minimum of 45 business days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognizable and unusable. This is necessary to establish a timeframe that the testing laboratory must keep the reserve sample for that allows sufficient time for the Bureau to verify results and to ensure that questionable samples can be reanalyzed.

Proposed subsection (b) specifies that the laboratory must store the reserve sample in a secure manner that prohibits sample degradation, contamination, and tampering. The reserve sample must be as close to the original sample as possible in the event that more analyses must be performed. This is necessary to preserve the integrity of the reserve sample if additional testing is deemed necessary so that the results will be representative of the associated batch.

Proposed subsection (c) requires that the testing laboratory provide the reserve sample to the Bureau upon request. This is necessary to inform the testing laboratory that the Bureau may request and shall be provided the reserve sample.

§ 5729. Laboratory Quality Assurance (LQA) Program

Proposed section 5729 would establish a laboratory quality assurance program. This is necessary to ensure that testing laboratories produce reliable and valid analytical data. As

there are no established laboratory quality assurance programs for the testing of cannabis, it is necessary for each laboratory to develop its own program.

Proposed subsection (a) requires the laboratory to develop and implement a quality assurance program that is sufficient to ensure valid results. It is the laboratory's responsibility to ensure the data and measurements they produce are of known accuracy and precision and all steps in the analytical process can be traced back. Implementing such a program is a standard practice that most reliable laboratories follow.

This provision and all the requirements listed are necessary because a quality assurance program encompasses a range of activities that enables a laboratory to achieve and maintain a high level of accuracy and proficiency despite changes in test methods and volumes of matrices analyzed

Proposed subsection (a)(1) requires the LQA program manual to include quality control procedures. This includes using proper quality control samples at a frequency that allows for verification of data produced, which would, at minimum, include those in section 5729 to verify the accuracy of the analytical data.

Proposed subsection (a)(2) requires the LQA program manual to include laboratory organization and personnel training and responsibilities. Sustaining high quality personnel management is important for quality assurance. This part of the manual should address persons responsible for carrying out corrective actions when problems are identified. The environment in which the work is conducted must be well controlled. It should be clean and tidy, have adequate space in which to work without risk to employees or to the analytical sample, and there should be sufficient storage space for glassware, chemicals, samples, and consumables. It is also essential that there are adequate numbers of appropriately trained staff available to undertake all the required tasks. The laboratory should provide and train the laboratory employees so that they have the proper knowledge to perform their duties. These measures will work to prevent errors during analytical work.

Proposed subsection (a)(3) requires that the LQA program manual should include the objectives for measurement data to clarify what the data should look like and the minimum quality standards those data must meet. This is done by setting a measurement system that operates in a state of statistical control, meaning errors have been reduced to acceptable levels. This is necessary to ensure the quality of data.

Proposed subsection (a)(4) requires the LQA program manual address the traceability of all data and analytical results. The ability to trace data and results to determine whether there have been data errors is necessary, not just for the laboratory to assure quality data, but for the person or entity who requested the testing and for the Bureau. This subsection is necessary to ensure the laboratory and the Bureau, may go back and detect measurement errors and procedure errors.

Proposed subsection (a)(5) requires the quality assurance program manual to address equipment preventative maintenance, calibration procedures, and frequency. This involves ensuring laboratory equipment can be maintained in the proper operating conditions such that the equipment is properly tuned and calibrated and reliable for the analyses undertaken. Calibration is the process of standardization of an instrument's response to perform quantitative analyses. The laboratory must determine what these standards are and maintain them at levels that are well within the limits normally established for the equipment or that are recommended for the care of the parts and accessories of equipment. Determining calibration curves is part of this procedure. These calibration standards should be checked by the supervisory or management laboratory employee and corrected if necessary. Frequent checks on the reliability of equipment must also be performed. This includes calibration checks on all relevant equipment, including balances. The frequency of these checks will depend on the SOP and stability of the equipment in question.

Proposed subsection (a)(6) requires performance and system audits. An audit may include tracing and analytical sample back through the system using the data package, from final report of measurements to sample gathering, and ensuring that all appropriate steps have been taken and records kept. This is a typical requirement for a regulated laboratory.

Proposed subsection (a)(7)—(a)(9) requires the LQA program manual address corrective action procedures, procedures or steps to change processes, and keeping of all records. This is a typical requirement for a regulated laboratory. Furthermore, corrective action documents the steps taken to resolve the cause of noncompliance with a requirement, standard, or procedure and prevent the recurrence of the same or similar cause of nonconformance.

Proposed subsection (a)(10) requires the LQA program manual to address the standardization of testing procedures established in the SOP of the laboratory. This is a typical requirement for a regulated laboratory.

Proposed subsection (a)(11) requires the LQA program manual to address method validation. This requirement would enable the Bureau to ensure methods used in analyses are properly validated in compliance with the proposed regulations described in section 5713.

Proposed subsection (b) specifies the duty and the role of the supervisory or management laboratory employee on the LQA program management. The supervisory or management laboratory employee is responsible for annual review, amending and approval of the manuals, if necessary. This management will cover any changes of the SOPs, laboratory equipment, or the supervisory or management laboratory employee.

§ 5730. Laboratory Quality Control (LQC) Samples

This proposed section specifies the importance, types, roles, and application of the quality control samples for the analysis of a testing laboratory. Proposed subsections (a)—(d)

establish the necessary types and numbers of quality control samples that must be included in analytical sample batches in both potency and contaminants analyses. The quality control samples must be prepared using the standard operating procedure, and most quality control samples, except the reagent blank samples and calibration standard samples, must be prepared using the same sample preparation method as the primary sample.

Proposed subsection (a) specifically requires that a testing laboratory use quality control samples in the performance of each assay for chemical and microbiological analyses. This is necessary because quality control sample results are used to ensure that data released by the testing laboratory is valid, reliable and reproducible. Quality control samples are used to measure method accuracy, precision, contamination, and matrix effects. The requirement for the testing laboratories to use quality control samples in every analytical batch is also necessary to be able to trace the integrity of the data and to hold laboratories accountable for testing, thus deterring testing laboratories from dry-labbing (“dry-labbing” is the act of delivering fictional results in lieu of performing actual laboratory testing).

Proposed subsection (b) specifically requires a testing laboratory to analyze quality control samples in the exact same manner as the test samples to validate and verify the laboratory testing results. It is necessary for quality control samples to be handled and prepared in the same way that primary samples are to confirm or “verify” that the validated method works. Furthermore, this is necessary because if a quality control sample result does not meet the acceptance criteria, then they must locate and remedy the problem. Quality control sample results are used for monitoring the continuing validity or legitimacy of analytical methods. It is necessary to include quality control samples in every analytical batch because quality control is an essential aspect of ensuring that data released are valid. Quality control samples are used to measure accuracy, precision, contamination, and matrix effects.

Proposed subsection (c) specifically requires that a testing laboratory use negative and positive controls for each target organism with every batch of samples tested for microbials. This requirement is necessary because these types of quality control samples are used to confirm or “verify” that the validated method works.

Proposed subsection (d) specifically requires that if the result of the microbial analyses is outside the specified acceptance criteria in the following table, the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria. This requirement is necessary to ensure the integrity of the test results. The integrity of analytical test results related to cannabis goods is very important as the consumer will rely on the truthfulness of the test results. If analytical test results are altered or skewed, this may pose a significant public health safety risk.

The corrective action requirements in the table will ensure that all licensed testing laboratories are using the same standards and actions to remedy issues.

| Laboratory Quality Control Sample | Acceptance Criteria | Corrective Action |
|--|---|---|
| Positive control | Produces expected result, positive result | Re-prep and reanalyze the entire analytical batch, once. If problem persists, locate and remedy the source of unexpected result, then re-prep samples and reanalyze with a new set of controls. |
| Negative control | Produces expected result, negative result | Re-prep and reanalyze the entire analytical batch, once. If problem persists, locate and remedy the source of unexpected result, then re-prep samples and reanalyze with a new set of controls. |
| Laboratory duplicate sample | Sample results must concur | Reanalyze sample and associated duplicate sample once. If problem persists re-prep samples and reanalyze. |

Proposed subsection (e) requires that a testing laboratory run quality control samples with every analytical batch of samples. It specifically requires the laboratory to prepare and analyze at least one of each of the following LQC samples for each analytical batch within each set of 20 samples – method blank; LCS; and laboratory duplicate sample or matrix spike. For chemical analyses, this level sufficiently demonstrates the validity of sample results.

Proposed subsection (e)(1) specifies the use of the method blank samples for quality control during chemical analysis. Method blank samples show whether laboratory contamination caused false positive results. A minimum of one method blank should be analyzed with each analytical batch of 20 samples or less. This is standard in environmental labs. The method blank sample should not yield a value higher than that allowed by the acceptance criteria. If this occurs, the laboratory shall re-prepare the batch and then re-run that batch. This is necessary because if the method blank is contaminated, it is very possible that contamination is coming from a part of the preparation process, or the instrument, and that same contamination may be present in samples.

Proposed subsection (e)(2) specifies the use of a laboratory control sample (LCS) for quality control during chemical analysis. The primary purpose of the laboratory control sample is to demonstrate that the laboratory can perform the overall analytical approach in

a matrix free of interferences and its analytical system is in control. This is standard in environmental labs. An LCS is a measure of accuracy of the method, and is used to establish the continued validity of the method being used by the laboratory.

Proposed subsection (e)(3) would require a replicate sample or a matrix spike sample be run with each analytical batch of 20 samples or less. Replicate samples are used as one form of quality control in each batch. Because the samples are analyzed using the same method, equipment, and reagents, the same bias should affect all results. Consequently, replicate analyses are only useful for checking sampling analysis, analytical precision, and reproducibility. Matrix spike samples verify the analytical accuracy and precision and/or test for matrix effects. (See explanation in definitions section for “matrix spike sample.”)

Proposed subsection (f) would require that the laboratory shall analyze a continuing calibration verification (CCV) sample at the beginning of each analytical sequence and every 10 samples thereafter. This is necessary to ensure that the calibration of the instrument is still valid. For cannabis matrices in particular, that are commonly known to have many interferences and can often be concentrates such as oils, it is important that this is checked at the beginning and end of every 10 samples run on the instrument. It was determined that the insertion of a CCV every 10 samples was the most appropriate because the number of QC samples was reduced in half after the removal of the field duplicate analysis. A CCV is used as a check standard and it is important to ensure that the instrument performance is optimized and that there is no carry over from a previous sample that may have had a high analyte concentration, subsequently contaminating the next sample. Using CCVs as QC samples ensures data quality and integrity.

Proposed subsection (g) in the first part of the table would require that the acceptance criteria of the method blank sample may not exceed the LOQ. If the method blank does exceed the LOQ, then the testing lab needs to follow the prescribed corrective action procedures, which include re-analyzing the extracts and/or re-prepping and then reanalyzing the entire batch. This is necessary because if there is contamination in the method blank above the LOQ, the laboratory may report data for the samples that is biased high. This contamination may be coming from something in the lab, rather than the actual sample. The laboratory must locate and remedy the source of contamination before reporting out any results.

Proposed subsection (g) in the second line of the table would require that the acceptance criteria of the laboratory control sample (LCS) is a percent recovery of between 70% - 130% for all analytes reported. If the LCS does not meet this acceptance criteria, then they must follow the prescribed corrective actions which include reanalyzing the batch, then re-prepping and reanalyzing the entire batch, if necessary. The lab may also rerun a calibration curve, and then reanalyze the samples if the problem persists. The primary purpose of the laboratory control sample is to demonstrate that the laboratory can perform

the overall analytical approach in a matrix free of interferences and its analytical system is in control. This is standard in environmental labs. An LCS is a measure of accuracy of the method, and is used to establish the continued validity of the method being used by the laboratory.

Percent recovery (%R) must be within 70% and 130% and shall be calculated as follows:

$$\%R = ([SSR - SR]) / SA \times 100$$

where

SSR = Spiked sample result

SR = Sample result

SA = Spike added

The spike level should be at or near midrange of the calibration.

This is a standard quality control measure, and the acceptable values proposed here (70% to 130%) are based on a published method in a water matrix from the US Environmental Protection Agency¹¹⁷ and methods for drug testing (content uniformity) from US Food and Drug Administration.¹¹⁸

Proposed subsection (g) specifies the acceptance criteria and the corrective action procedures of the replicate sample. Because the samples are analyzed using the same method, equipment, and reagents, the same bias should affect all results. Analytical precision is a measure of the reproducibility of data and is assessed by analyzing two samples that are intended to be identical. Any significant differences between the samples indicate an unaccounted-for factor or a source of bias. Because the samples are analyzed using the same method, equipment, and reagents, the same bias should affect all results. Duplicate samples are important because they are used, in part, to evaluate the quality of the data reported.

Proposed subsection (g) in the fourth line of the table would require the acceptance criteria and the corrective action procedures of the matrix spike sample. If the matrix spike is outside the specified acceptance criteria, which is 70-130% recovery, then the prescribed

¹¹⁷ US Environmental Protection Agency, Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Postcolumn Derivatization, Method 532.1, EPA # 815-B-01-002, September 2001.

<https://www.epa.gov/sites/production/files/2015-06/documents/epa-531.2.pdf>. Accessed March 28, 2017.

¹¹⁸ US Food and Drug Administration, ORA Laboratory Procedure: Methods, Method Verification and Validation, Effective Date:10-01-03, Revised: 08-29-14.

<https://www.fda.gov/downloads/ScienceResearch/FieldScience/LaboratoryManual/UCM092147.pdf>. Accessed March 28, 2017.

corrective actions must be done until this LQC sample falls within the specified criteria. Matrix spike (MS) analysis is used to assess the accuracy (MS) of the analytical methods in the sample matrix. The results of the analysis of the unspiked environmental sample are compared to the MS analysis results, and percent recovery¹¹⁹ of each spike is calculated to determine the accuracy of the analysis. Matrix Spike samples are important because they are used, in part, to evaluate the quality of the data reported.

Percent recovery (%R) must be within 70% and 130% and shall be calculated as follows:

$$\%R = ([SSR - SR]) / SA \times 100$$

where

SSR = Spiked sample result

SR = Sample result

SA = Spike added

The spike level should be at or near midrange of the calibration.

This is a standard quality control measure, and the acceptable values proposed here (70% to 130%) are based on a published method in a water matrix from the US Environmental Protection Agency¹¹⁹ and methods for drug testing (content uniformity) from US Food and Drug Administration.¹²⁰

Proposed subsection (g) addresses how to analyze calibration standards. When analyst prepares the working standards by dilution based on the standard operating procedure, the linearity and the range of the standards must be established prior. Regularly checking the standard solutions may be needed because the old solutions could have deteriorated. It is also needed to verify the storage conditions, the age of solutions, and their expected shelf-life. A calibration standard sample of the middle concentration may be used at first or between the analytical batches as an initial certification verification sample or continuous certification verification sample to check the accuracy and the system stability for the analysis.

¹¹⁹ US Environmental Protection Agency, Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Postcolumn Derivatization, Method 532.1, EPA # 815-B-01-002, September 2001.

<https://www.epa.gov/sites/production/files/2015-06/documents/epa-531.2.pdf>. Accessed March 28, 2017.

¹²⁰ US Food and Drug Administration, ORA Laboratory Procedure: Methods, Method Verification and Validation, Effective Date:10-01-03, Revised: 08-29-14.

<https://www.fda.gov/downloads/ScienceResearch/FieldScience/LaboratoryManual/UCM092147.pdf>. Accessed March 28, 2017.

The corrective action requirements in the table will ensure that all licensed testing laboratories are using the same standards and actions to remedy issues.

| Laboratory Quality Control Sample | Acceptance Criteria | Corrective Action |
|--|--------------------------------------|---|
| Method blank sample | Not to exceed LOQ | Reanalyze entire analytical batch once. If method blank is still greater than the LOQ for any analyte, locate the source of contamination then re-prep samples and reanalyze. |
| LCS | Percent recovery 70% - 130% | Reanalyze the entire analytical batch, once. If problem persists, re-prep samples and reanalyze or re-run the initial calibration curve. |
| Laboratory duplicate sample | RPD \leq 30% | Reanalyze sample and associated duplicate sample once. If problem persists re-prep samples and reanalyze. |
| Matrix spike sample | Percent recovery between 70% to 130% | Reanalyze sample and associated matrix spike sample once. If problem persists re-prep samples and reanalyze. |
| CCV | Percent recovery between 70% to 130% | Reanalyze all samples that followed the last CCV that met the acceptance criteria. If CCV still fails, re-run the initial calibration curve and all samples in the analytical sequence. |

Proposed subsection (h) requires that if any analyte is detected above the action level, as described in this chapter, the sample shall be re-prepped and reanalyzed in duplicate within another analytical batch. This is necessary because the requirement to collect and analyze a field duplicate samples was removed from the emergency regulations, but this new necessary requirement ensures the validity of the analytical results.

Proposed subsections (h)(1)—(h)(2) detail the requirements for the RPD and acceptance criteria for the re-prepped sample and its associated replicate. This is necessary to ensure the validity of the analytical results.

Proposed subsection (i) requires that if any LQC sample produces a result outside of the acceptance criteria the laboratory cannot report the result and the entire batch cannot be released for retail sale. The laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria. This is necessary for clarification to inform the laboratory on what they may report and what results they would be prohibited from reporting.

Proposed subsection (j) requires that if the laboratory determines that the result is a false-positive or a false-negative, The Bureau may request the laboratory to re-sample or re-test. This is necessary to include for clarification purposes and to inform the laboratory of potential Bureau requests related to analytical testing.

Proposed subsection (k) requires the laboratory to compile and generate one quality control sample report that includes quality control parameters and measurements, analysis date, and matrix. This subsection is necessary because a laboratory must have a record showing the quality control results so that data can be used to evaluate the accuracy and precision of the primary sample results. This is also necessary to provide clarification that one LQC report for the entire batch shall be compiled. It is necessary to require the laboratories to compile one LQC report per batch to also simplify and verify the validity of the quality control data.

§ 5731. Limits of Detection (LOD) and Limits of Quantitation (LOQ) for Quantitative Analyses

Proposed subsection (a) specifies that the laboratory is responsible to calculate and establish its own limits of detection (LOD) for the test following one of the options in the subsections (a)(1)—(3). There are several methods and approaches from various sources, such as the US Environmental Protection Agency (EPA), the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Association of Official Analytical Chemists (AOAC), and the American Chemical Society (ACS) to determine LOD for analytical quantitation in different matrices and using different instruments^{121,122,123}. LOD is the lowest quantity of a substance or analyte that can be distinguished from the absence of the substance within a stated confidence limit. It is the

¹²¹ US Environmental Protection Agency, Definition and Procedure for the Determination of the Method

Detection Limit, Revision 2. <https://www.epa.gov/cwa-methods>

¹²² Alankar Shrivastava, Methods for the Determination of Limit of Detection and Limit of Quantitation of the Analytical Methods, Chronicles of Young Scientists, Vol. 2, Issue 1, Jan-Mar 2011

¹²³ 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

one of the important performance characteristics in method validation and help to make decisions based on the uncertainties and limitations associated with these reporting limits¹²⁴.

There are no universally accepted procedures for calculating LOD, and the testing laboratories choose different approaches or their own in-house methods to determine LOD. To ensure the testing laboratories follow a more standardized approach, the Bureau listed three options in this proposed section to guide testing laboratories in the calculation of LOD.

Proposed subsection (a)(1) guides the LOD calculation based on signal-to-noise ratio. The determination of the signal-to-noise ratio is performed by comparing measure signals from samples with known low concentrations of analytes with those of method blank samples and establishing the minimum concentration at which the analyte can be reliably detected. A signal-to-noise ratio of between 3:1 and 2:1 is acceptable for estimating the LOD. This proposed method is described by the US Food and Drug Administration (FDA)¹²⁵.

Cannabis goods are closer to food products than environmental samples such as water or soil, and therefore the Bureau proposes that testing laboratory determine LODs based on FDA guidance.

Proposed subsection (a)(2) guides the LOD calculation based on the standard deviation of the response and the slope of calibration curve. Standard deviation of the response can be determined using minimum 7 spiked blank samples or the standard error of the calibration curve can be used instead of the standard deviation. The LOD may be calculated as follows:

$$\text{LOD} = 3.3 \times \text{standard deviation of the response} / \text{slope of the calibration curve}$$

This proposed method is also described by the US Food and Drug Administration (FDA)¹²⁵. Cannabis goods are closer to food products than environmental samples such as water or soil, and therefore the Bureau proposes that testing laboratory determine LODs based on FDA guidance.

¹²⁴ Wisconsin Department of Natural Resources Laboratory Certification Program, Analytical Detection Limit Guidance & Laboratory Guide for Determining Method Detection Limits, April 1996. <http://dnr.wi.gov/regulations/labcert/documents/guidance/-LODguide.pdf>

¹²⁵ US Food and Drug Administration, Department of Health and Human Services, Guidance for Industry,

Q2B Validation of Analytical Procedures: Methodology, November 1996.

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073384.pdf>

Proposed subsection (a)(3) introduces a third option for LOD calculation. Because in some situations there may be some technical difficulties with using the FDA calculations or not available to get the baseline noise data if the method does not use chromatographic technique, the Bureau offers more options as other methods published by the US FDA or the US EPA such as method detection limit (MDL) using blanks and spike samples. Another reason for this third option is that some laboratories may already have procedures to determine LOD based on reliable published methods.

It is proposed that all testing laboratories must choose one of these three options for LOD to produce valid testing results and avoid poor data quality and possible result fabrications.

Proposed subsection (b) specifies that the laboratory is responsible to calculate and establish its own limits of quantitation (LOQ) for the test following one of the options in the subsections (b)(1) ~ (3). There are several methods and approaches from various sources, such as the US Environmental Protection Agency (EPA), the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Association of Official Analytical Chemists (AOAC), and the American Chemical Society (ACS) to determine LOQ for analytical quantitation in different matrices and using different instruments¹²⁶¹²⁷¹²⁸. LOQ is the minimum concentration of analyte in a specific matrix that can be reliably quantified. It is the one of the important performance characteristics in method validation and helps to make decisions based on the uncertainties and limitations associated with these reporting limits¹²⁹.

There are no universally accepted procedures for calculating LOQ, and the testing laboratories choose different approaches or their own in-house methods to determine LOQ. To ensure the testing laboratories follow a more standardized approach, the Bureau listed three options in this proposed section to guide testing laboratories in the calculation of LOQ.

Proposed subsection (b)(1) guides the LOQ calculation based on signal-to-noise ratio. The determination of the signal-to-noise is performed by comparing measuring signals from samples with known low concentrations of analyte with those of blank samples and

¹²⁶ US Environmental Protection Agency, Definition and Procedure for the Determination of the Method

Detection Limit, Revision 2. <https://www.epa.gov/cwa-methods>

¹²⁷ Alankar Shrivastava, Methods for the Determination of Limit of Detection and Limit of Quantitation of the Analytical Methods, Chronicles of Young Scientists, Vol. 2, Issue 1, Jan-Mar 2011

¹²⁸ 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

¹²⁹ Wisconsin Department of Natural Resources Laboratory Certification Program, Analytical Detection Limit Guidance & Laboratory Guide for Determining Method Detection Limits, April 1996.

<http://dnr.wi.gov/regulations/labcert/documents/guidance/-LODguide.pdf>

establishing the minimum concentration at which the analyte can be reliably quantified. A signal-to-noise ratio of 10:1 is the minimum for reliable quantitation.

Proposed subsection (b)(2) guides the LOQ calculation based on the standard deviation of the response and the slope of calibration curve. The standard deviation of the response can be determined from minimum 7 spiked blank samples or the standard error of the calibration curve can be used instead of the standard deviation. The LOQ may be calculated as follows:

$$\text{LOQ} = (10 \times \text{standard deviation of the response}) / \text{slope of the calibration curve}$$

Proposed subsection (b)(3) introduces a third option for LOQ calculation. Because in some situations there may be some technical difficulties with using the FDA calculations or not available to get the baseline noise data if the method does not use a chromatographic technique, the Bureau offers more options including methods published by the US FDA or the US EPA such as LOQ with a method detection limit (MDL) using blanks and spike samples. Another reason for this third option is that some laboratories may already have procedures to determine LOQ based on reliable published methods.

It is proposed that all testing laboratories must choose one of these three options for LOQ to produce valid testing results and avoid poor data quality and possible result fabrications.

§ 5732. Data Package

Proposed section 5732 specifies the required information that the testing laboratory must include in the data package for each batch of samples analyzed. Data packages are meant to be clear and detailed documents that capture the workflow and results of the samples tested. The section is necessary to systematically standardize data packages to include critical elements from testing laboratories that allows the Bureau to trace the integrity of the testing results.

Proposed subsection (a) enumerates the required information that the data package must contain and compile into one data package. This is necessary to inform the testing laboratory what they must include in a complete data package for each representative sample. It is necessary to include such documentation in the data package to detour testing laboratories from dry-labbing; dry-labbing is the act of delivering fictional results in lieu of performing actual laboratory testing. The integrity of analytical test results related to cannabis goods is very important as the patient/consumer will rely on the truthfulness of the test results. If analytical test results are altered or skewed, this may pose a significant public health safety risk.

Proposed subsection (a)(1) requires that the data package include the name, physical address, and license number of the testing laboratory that performed the analytical testing procedures. This is necessary to identify the laboratory responsible for sampling and testing

while enabling the Bureau to trace the integrity of the data and to hold the laboratory accountable for testing¹³⁰.

Proposed subsection (a)(2) requires that the data package include the name(s), title(s), and signature(s) of the laboratory employee(s) involved with any step during the analytical testing procedures. This will identify the person(s) responsible for sample preparation, analyses, data review, and final approval. This is necessary to enable the Bureau to identify the parties responsible in the event or incident of alleged noncompliance, errors, contamination, or similar issues¹³¹.

Proposed subsection (a)(3) requires that the data package include all sample results and laboratory quality-control (LQC) sample results from the analytical batch. It is necessary for the data package to include sample results because it is the most desired, critical element of the data package. It is also necessary to include any and all quality control sample data in the data package to ensure that the data released is valid by measuring accuracy, precision, contamination, and matrix effects¹³². This level sufficiently demonstrates the validity of sample results.

Proposed subsection (a)(4) requires that the data package include the date stamped raw data for each sample. Raw data can include, but is not limited to, hand-written calculations, test method worksheets or forms used for sample identification or characterization, sample preparation worksheets, and laboratory notebook pages containing pertinent information related to sample preparation. Instrument raw data can include, but is not limited to, analytical instrument print-outs with analyte concentrations, sample preparation system print-outs, and chromatograms¹³³. It is necessary to include such documentation in the data package to be able to trace the integrity of the data and to hold laboratories accountable for testing, thus detouring testing laboratories from dry-labbing. Record retention pertaining to traceability is also required by ISO/IEC 17025 and ISO/IEC 17025 accreditation for cannabis testing laboratories is mandated by Business and Professions Code section 261000.

Proposed subsection (a)(5) specifically requires that the data package include the instrument test method with parameters, if available. An instrument test method with parameters typically specifies how the analytical instrument is to operate during sample analysis. For example, this would specify column flow rate and temperature, solvent flow rate and/or ratio, auxiliary pump settings, injection volume and draw speed. It is necessary to include these in the data package to affirm that the correct test method and parameters were used in the sample analysis.

Proposed subsections (a)(6) specifically requires that the data package include the instrument tune report, if available. An instrument tune report can include, but is not limited to, quadropole/octopole parameters and detector parameters. It is necessary to include a tune report in the data package to affirm that the instrument was primed or tuned

¹³⁰ ISO/IEC 17025:2005 sub-clause 5.10.2 Test reports and calibration certificates

¹³¹ ISO/IEC 17025:2005 sub-clause 5.10.2 Test reports and calibration certificates

¹³² ISO/IEC 17025:2005 sub clause 5.9 Assuring the quality of test and calibration results

¹³³ ISO/IEC 17025:2005 sub clause 5.6: Measurement traceability

to specific qualifications that optimized the analytical instrumentation before the analysis began.

Proposed subsection (a)(7) specifically requires that the data package include instrument calibration data, if available. Instrument calibration data is used to measure the precision and accuracy of equipment and proper calibration of an instrument allows one to produce valid data for future reference. It is necessary to include instrument calibration data because this assures that the measurements or results are accurate and within the specification limits.

Proposed subsection (a)(8) requires that the data package include the LQC sample report. The LQC sample report shall include LQC acceptance criteria, measurements, analysis dates, and matrix types. This is necessary because this demonstrates how the testing laboratory achieves accurate results while ensuring the data from the quality-control samples are precise.

Proposed subsections (a)(9) specifically requires that the data package include the worksheets, forms, pictures, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis. The information about the quality control samples acceptance criteria, is necessary to ¹³⁴assure the quality of test results, refer to section 5730 for more details. ¹³⁵This is necessary because this is how the testing laboratories achieve measurement traceability for its testing measurements. ISO/IEC 17025 covers the selection, identification, use, initial/continuing calibration checks, handling, transport and storage (control and maintenance), of the laboratory's certified and standard reference materials (CRMs and SRMs), calibration standards and reference cultures used to ensure data integrity. It is also necessary to include such documentation in the data package to ensure the integrity of the data and to hold laboratories accountable for testing, thus detouring testing laboratories from dry-labbing.

Proposed subsection (a)(10) specifically requires that a laboratory include the analytical sequence, also referred to as a run log, if available. This is necessary to ensure that the testing laboratories are analyzing samples in the correct order – not randomly inserting samples without the proper associated LQC samples¹³⁶. Both qualitative and quantitative testing methods must meet system suitability requirements that are needed for the verification of methods per ISO/IEC 17025 sub clause 5.4¹³⁷. Although the order in which the samples are analyzed is not specified, LQC sample requirements are needed. The laboratories will determine the order in which samples are to be analyzed according to their method specific standard operation procedure (SOP). ISO/IEC 17025 accreditation will help ensure that the testing laboratory's SOPs comply with standards. It is necessary to comply with ISO/IEC 17025 standards as mandated by the authorizing statute, Business and Professional Code section 26100.

¹³⁴ ISO/IEC 17025:2005 sub clause 5.9 Assuring the quality of test and calibration results

¹³⁵ ISO/IEC 17025:2005 sub clause 5.6: Measurement traceability

¹³⁶ ISO/IEC 17025:2005 sub clause 5.9 Assuring the quality of test and calibration results

¹³⁷ ISO/IEC 17025:2005 sub clause 5.4: Test and calibration methods and method validation

Proposed subsection (a)(11) requires that the data package include the shipping manifest, as required under this division. This is necessary to track the movement and proper documentation of samples.

Proposed subsection (a)(12) requires that the data package include the chain of custody (COC) form. The COC form includes information about the sample source, distributor, and manufacturer and accounts for the collection, storage, transfer or transport, and condition of the sample. This is necessary because it will document if the integrity of the sample has been maintained throughout the testing process.

Proposed subsection (a)(13) requires that the data package include the certificate of analysis (COA) for each sample in the analytical batch. The COA is the report prepared for a sample that includes information about the analyses performed and results obtained by the testing laboratory. This is necessary because it provides the sample's testing results and completes the data package by including the report that will be linked to that sample and its associated batch.

Proposed subsection (b) enumerates the duties and responsibilities of the laboratory supervisor or management employee related to the data package. This is necessary to establish the role and responsibilities of the laboratory supervisor or management employee for the completion of the data package.

Proposed subsection (b)(1) specifies that the laboratory supervisor or management employee shall review the results included in the data package and ensure they are correct and complete. This is necessary to ensure the laboratory supervisor or management employee evaluates the results included in the data package and confirms they are accurate.

Proposed subsection (b)(2) specifies that the laboratory supervisor or management employee shall verify that the results listed for each analysis are accurate, clear, unambiguous, and objectively reported. This is necessary to ensure the laboratory supervisor or management employee verifies the analysis records included in the data package are understandable to the requestor(s) of the data package.

Proposed subsection (b)(3) specifies that the laboratory supervisor or management employee shall approve the laboratory results by signing and dating the data package. This is necessary to ensure the laboratory supervisor or management employee is responsible for the validity of the laboratory's test results.

Proposed subsection (c) requires that the entire data package be kept for a minimum of seven years and be made available upon request by the Bureau. In general records related to cannabis shall be kept for a minimum of 7 years and shall be made available upon request by the Bureau. It is necessary to keep records for a minimum of 7 years because in the event of a safety recall and/or a trace-back or trace-forward investigation records related to cannabis may need to be referenced. Records pertaining to cannabis shall be kept for a minimum of 7 years as mandated in Business and Professional Code section 26160. To comply with statutory regulations the testing laboratory must make the data package available to the Bureau.

This is necessary to keep the entire data package for a minimum of seven years in the event of a safety recall or a trace-back investigation where the data packages may need to be referenced.

§ 5733. Required Proficiency Testing

This proposed section specifies the requirement for the testing laboratories to conduct regularly scheduled proficiency testing. The purpose of this requirement is to provide testing laboratories and the Bureau with objective evidence of a laboratory's capability to produce data that are both accurate and repeatable for the tests that the laboratory routinely conducts. Proficiency testing data can be used to demonstrate a laboratory's competence to clients, potential customers, accreditation bodies, and regulatory bodies. Participation in proficiency testing activities ensures that testing laboratories are consistently performing medicinal cannabis testing procedures properly. Through proficiency testing, a laboratory can verify its competence to perform the specific tasks that they are licensed to perform.

Proposed subsection (a) specifies the frequency of a laboratories shall participate in a proficiency testing program provided by an organization that operates in conformance with the requirements of ISO/IEC 17043. The subsection states that a laboratory shall participate in a proficiency testing program at least once every six months. This can be a proficiency test for any one or multiple analytes. This subsection is necessary in order to increase confidence in the reliability of the data laboratories produce.

Proposed subsection (b) specifies that the laboratory shall, successfully participate in a proficiency testing program for each of the following test methods: (1) Cannabinoids; (2) Heavy metals; (3) Microbial impurities; (4) Mycotoxins; (5) Residual pesticides; (6) Residual solvents and processing chemicals; and (7) If tested, terpenoids. This is necessary to ensure that the laboratories are all being evaluated on the same test methods.

Proposed subsection (c) species that the laboratory shall report all analytes available by the proficiency testing program provider and for which the licensee is required to test as required under this chapter. This requirement ensures that the laboratories are reporting all of the required data available by the proficiency testing provider.

Proposed subsection (d) specifies that the laboratory shall participate in the proficiency testing program by following the laboratory's existing SOPs for testing cannabis goods. This requirement ensures that the proficiency test results are representative of the laboratory's routine analytical methods. This requirement ensures that the methods and equipment being evaluated during the proficiency testing are the same methods and equipment used in the laboratory's usual testing. By requiring this, this proposed subsection ensures that the proficiency testing is evaluating the methods and equipment used by the testing laboratory in testing cannabis goods.

Proposed subsection (e) specifies that laboratories shall rotate the proficiency tests among their staff in the laboratory so all staff performing the methods have participated in a proficiency test over a reasonable time period, which shall be outlined in the quality-assurance manual required under these regulations. This is necessary to ensure that the methods used by the laboratory and the results produced by the tests are accurate and

trustworthy. Also, it is necessary to routinely evaluate staff to verify that procedures are conducted competently.

Proposed subsection (f) specifies the requirement that laboratory employees who participated in a proficiency test sign the corresponding analytical report or attestation statement stating that the proficiency test was conducted in the same manner as the laboratory ordinarily conducts testing of cannabis goods. This requirement ensures that the proficiency test adequately represents the testing activities routinely done in the laboratory.

Proposed subsection (g) specifies that a supervisory or management laboratory employee shall review and verify the accuracy of results reported for all proficiency testing program samples analyzed. This requirement provides for an added layer of review of sample analysis and test-result reporting. This requirement also ensures that the laboratory supervisors or management is involved and informed of proficiency testing occurring at the laboratory.

Proposed subsection (h) specifies the requirement that the laboratory shall request proficiency testing program provider send results concurrently to the Bureau, if available. Or the laboratory shall provide proficiency testing program results to the Bureau within 3 business days after the laboratory receives notification of their test results from the proficiency testing program provider. This requirement ensures that the Bureau is well informed of the testing laboratory's proficiency in conducting routine testing of cannabis goods.

§ 5734. Satisfactory and Unsatisfactory Proficiency Test Performance

Proposed section 5734 specifies satisfactory and unsatisfactory participation in a proficiency test program performed by the testing laboratory. Proficiency test programs must cover the scope of laboratory testing as it pertains to testing cannabis goods. Typically, each analyte is scored separately in proficiency tests, allowing a testing laboratory to receive "satisfactory" and/or "unacceptable", "questionable", or "unsatisfactory" results for different analytes tested in a specific method. Proficiency testing is a key means of obtaining evidence of laboratory competence.

Proposed subsection (a) indicates that a testing laboratory that has received a "satisfactory" proficiency test result, or otherwise proficient performance determination by the proficiency test program provider, shall be deemed to have successfully participated in proficiency test program.

This provision is necessary to have successful participation or "satisfactory" proficiency testing data because this is used to demonstrate the testing laboratory's competence when testing samples and reporting results.

Proposed subsection (b) indicates that a testing laboratory that has received an "unacceptable," "questionable," "unsatisfactory," or otherwise deficient proficiency test result is not permitted to continue reporting results for those analytes. An unsatisfactory result in proficiency testing is an indication that the results from that particular test may not be reliable. Testing laboratories should not report results for test that have been deemed

unsatisfactory. This provision is necessary to have laboratories with unsatisfactory proficiency testing results to cease reporting results for that test, as incorrect or inaccurate results could pose a significant public health safety risk.

Proposed subsection (c) enumerates the conditions that a testing laboratory who has received an “unacceptable,” “questionable,” “unsatisfactory,” or otherwise deficient proficiency test result must meet in order to resume reporting test results for that analyte. An unsatisfactory result in proficiency testing is an indication that the results from that particular test may not be reliable. Testing laboratories should not perform tests that have been deemed unsatisfactory until they have remediated the problem and can accurately test for each analyte. This provision is necessary to maintain the integrity and reliability of the testing process. Reporting results for testing should not occur until the laboratory is able to correct the deficiencies that led to the unsatisfactory proficiency test result.

Proposed subsection (c)(1) requires a testing laboratory that has received an unsatisfactory proficiency test result to remedy the cause of failure for each analyte. This is necessary because reliability of test results is paramount, and a testing laboratory should not be allowed to provide testing services for specific analytes if their methods have been deemed “unacceptable”, “questionable”, “unsatisfactory”, or otherwise deficient.

Proposed subsection (c)(2) requires a testing laboratory that has received an unsatisfactory proficiency test result to submit a written corrective action report to the Bureau, indicating how the laboratory successfully fixed the cause of failure. This is necessary to ensure that licensed laboratories that have received unsatisfactory proficiency test results are taking the required action to correct the deficiencies.

§ 5735. Laboratory Audits

Proposed section 5735 specifies the requirement for testing laboratories to conduct internal audits. Internal audits allow the laboratories to verify that their operations are being conducted as planned and that operations continue to comply with the requirements of the laboratory’s management system and ISO/IEC 17025 standards. When audit findings cast doubt on the effectiveness of the operations or on the validity of the laboratory’s test results, the laboratory shall take timely corrective action. The areas of activities audited, the audit findings, and corrective actions that arise from them shall be recorded. Follow-up activities shall verify and record the implementation and effectiveness of the corrective action taken. This is necessary to ensure that the testing laboratories are operating as planned and are providing valid results.

Proposed subsection (a) requires the laboratory to conduct an internal audit annually, or as required by the ISO/IEC 17025 accrediting body. Regular internal audits are important to demonstrate the effective operation of the testing laboratory and the reliability of that laboratory’s test results. One year is the longest amount of time that the testing laboratory should go in between conducting internal audits. This proposal is necessary to specify the frequency that the testing laboratories must perform internal audits.

Proposed subsection (b) specifies that the requirements for internal audits performed by the testing laboratories must comply with the ISO/IEC 17025 internal audit standards. It is necessary and appropriate to use the ISO/IEC 17025 internal audit standards because ISO/IEC 17025 accreditation is required for a cannabis testing laboratory license.

Proposed subsection (c) requires the laboratory to provide the results of internal audits to the Bureau within three business days. The performance of regular internal audits is important and allows the Bureau to verify that the laboratory's operations continue to meet all of the requirements for licensure. This is necessary to ensure that the Bureau is informed of the validity of the licensee's operations in a timely manner.

Proposed subsection (d) requires the laboratory to provide the results of the ISO/IEC 17025 accrediting body on-site audits to the Bureau within three business days. The performance of regular audits conducted by the accrediting body is fundamental to the accrediting body ability to verify that the laboratory's operations continue to meet all of the requirements for ISO/IEC 17025 accreditation. This is necessary to ensure that the Bureau is informed of the validity of the licensee's operations in a timely manner.

§ 5736. General Laboratory Employee Qualifications

Section 5736 specifies the qualifications required for general laboratory employees. It also specifies the laboratory's responsibility to adequately train employees and document their qualifications. This section is necessary to ensure that all cannabis testing laboratory employees meet the specific qualifications. The benefit of this section is that laboratories will ensure that all employees are qualified to engage in testing activities.

Proposed subsection (a) specifies that a person aged 21 years or older is eligible for employment as a cannabis testing laboratory employee. Under California law, adult-use cannabis goods may only be possessed by people aged 21 years or older. Possession of medicinal cannabis by people younger than age 21 is permitted only if such person obtains a medicinal cannabis recommendation. This proposal is necessary to prevent the unlawful possession of cannabis goods by an underaged person.

Proposed subsection (b) requires the laboratory to develop and implement an employee training program that ensures the employees are competent when they perform their assigned functions. This is necessary because it places the responsibility of training on the testing laboratory while ensuring the training program will enable employees to perform their functions.

Proposed subsection (c) requires the laboratory to ensure and document that each employee meets the employee qualifications. This is necessary because it allows the laboratory to demonstrate their employees meet the specified qualifications in this section.

§ 5737. Supervisor or Management Responsibilities and Qualifications

Proposed section 5737 specifies the responsibilities typically performed by the laboratory supervisor or management and the education, training, and experience qualifications for such a position. It is important to clarify the acceptable levels of education and experience that must be possessed by the laboratory supervisor or management, as the position's responsibilities are important in the daily operations of the testing laboratory. This section is necessary to ensure that the cannabis testing laboratory supervisory or management employees possess the requisite academic and professional qualifications necessary to perform the scientific duties and privileges associated with licensure.

Proposed subsection (a) enumerates the responsibilities that the laboratory supervisor or management employee shall fulfill. This is necessary to ensure that the laboratory supervisor or management employee relies on extensive experience and judgment to plan and accomplish responsibilities associated with licensure, including directing, establishing, and planning the overall policies and goals for a laboratory.

Proposed subsection (a)(1) specifies that the laboratory supervisor or management employee is responsible for overseeing and directing the scientific methods of the laboratory. This is necessary because the laboratory supervisor or management employees responsible for the testing performed by acting as the head of the laboratory and must be able to direct and manage the methods used.

Proposed subsection (a)(2) specifies that the laboratory supervisor or management employee is responsible for ensuring that the testing laboratory maintains a laboratory quality assurance program. This is necessary because the laboratory supervisor or management employee shall serve as a quality director by assuring high-quality data is created by the laboratory.

Proposed subsection (a)(3) specifies that the laboratory supervisor or management employee is responsible for providing ongoing and appropriate training to laboratory employees. This is necessary to ensure that the laboratory supervisor or management employee is training other employees in an appropriate and thorough way.

Proposed subsection (b) enumerates the varying levels of qualifications for a cannabis testing laboratory supervisor or management employee. This section is necessary to clarify the compliance standards for employing a laboratory supervisor or manager at a licensed cannabis testing laboratory.

Proposed subsection (b)(1) specifies that the level of postsecondary education that must be completed by a candidate for employment as a laboratory supervisor or management is a doctoral degree in a related field of study. This requirement is a tiered approach, if you have a higher education, less experience is needed. Education develops one's speed of learning and ability to learn at depth, thus less practical experience is needed because a course of education will bring a greater depth of understanding than experience can provide. This section is necessary to clarify one of the four ways in which an applicant for employment as a laboratory supervisor or management employee may qualify for employment as such.

Proposed subsection (b)(2) specifies the level of postsecondary education that must be completed by a candidate for employment as a laboratory supervisor or management is a master's degree in a related field of study. This requirement is a tiered approach, if you have a higher education, less experience is needed. Education develops one's speed of learning and ability to learn at depth, thus less practical experience is needed because a course of education will bring a greater depth of understanding than experience can provide. This section further specifies that after completing the requisite postsecondary education under this subsection, a person may be eligible for employment as a laboratory supervisor or management employee upon completion of two years of full-time practical experience performing analytical scientific testing. Two years full-time experience has been determined to be a sufficient amount of time and experience in a laboratory setting

needed to perform the necessary duties associated with the position coupled with completed education. This section is necessary to clarify one of the four ways in which an applicant for employment as a laboratory supervisor or management employee may qualify for employment as such.

Proposed subsection (b)(3) specifies the level of postsecondary education that must be completed by a candidate for employment as a laboratory supervisor or management is a bachelor's degree in a related field of study. This requirement is a tiered approach, if you have a higher education, less experience is needed. Education develops one's speed of learning and ability to learn at depth, thus less practical experience is needed because a course of education will bring a greater depth of understanding than experience can provide. This section further specifies that after completing the requisite postsecondary education under this subsection, a person may be eligible for employment as a laboratory supervisor or management employee upon completion of at least four years of full-time practical experience performing analytical scientific testing. Four years full-time experience has been determined to be a sufficient amount of time and experience in a laboratory setting needed to perform the necessary duties associated with the position coupled with completed education. This section is necessary to clarify one of the four ways in which an applicant for employment as a laboratory supervisor or management employee may qualify for employment as such.

Proposed subsection (b)(4) specifies the level of postsecondary education that must be completed by a candidate for employment as a laboratory supervisor or management is a bachelor's degree in any field. This requirement is a tiered approach, if you have a higher education, less experience is needed. Education develops one's speed of learning and ability to learn at depth, thus less practical experience is needed because a course of education will bring a greater depth of understanding than experience can provide. This section further specifies that after completing the requisite postsecondary education, a person may be eligible for employment as laboratory supervisor or management employee upon completion of eight years of full-time practical experience performing analytical scientific testing with a minimum of four years of the eight being full-time practical supervisory or managerial experience. Eight years full-time experience, including a minimum of four years practical supervisory or managerial experience has been determined to be a sufficient amount of time and experience in a laboratory setting needed to perform the necessary duties associated with the position coupled with education. This section is necessary to clarify one of the four ways in which an applicant for employment as a laboratory supervisor or management employee may qualify for employment as such.

§ 5738. Analyst and Sampler Qualifications

Proposed section 5738 specifies the required qualifications for laboratory analysts and samplers. This section is necessary to ensure that cannabis testing laboratory employees possess the requisite academic and professional qualifications necessary to perform the scientific duties and privileges associated with licensure.

Proposed subsection (a) specifies that the laboratory must employ an analyst who meets minimum qualifications. This is necessary to provide the laboratory director/supervisor and clients confidence in the analysts work.

Proposed subsection (a)(1) — (2) specifies that the laboratory must employ an analyst who at minimum earned a master's degree or a bachelor's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university; or completed 2 years of college or university education that included coursework in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 3 years of full-time practical experience. This requirement is a tiered approach, if you have a higher education, less experience is needed. Education develops one's speed of learning and ability to learn at depth, thus less practical experience is needed because a course of education will bring a greater depth of understanding than experience can provide. This subsection makes certain that analysts employed by the testing laboratories have met the necessary schooling and work experience requirements which will provide the laboratory director/supervisor and clients confidence in the analysts work. Three years full-time experience, including a minimum of two years college or university education has been determined to be a sufficient amount of time and experience in a laboratory setting needed to perform the necessary duties associated with the position. This requirement allows for employees who may have not completed their degree to work in a cannabis testing laboratory with adequate training for this specific position provided by supervisory or managerial employees.

Proposed subsection (b) specifies that the laboratory must employ a sampler who meets the minimum qualifications. This is necessary to provide the laboratory director/supervisor and clients confidence in the sampler's work.

Proposed subsection (b)(1) — (2) specifies that the laboratory must employ a sampler who at minimum completed 2 years college or university education; or earned a High School Diploma or passed a General Educational Development or High School Equivalency exam, plus at least 1 year of full-time practical experience. This requirement is a tiered approach, if you have a higher education, less experience is needed. Education develops one's speed of learning and ability to learn at depth, thus less practical experience is needed because a course of education will bring a greater depth of understanding than experience can provide. This subsection makes certain that samplers employed by the testing laboratories have met the necessary schooling and work experience requirements which will provide the laboratory director/supervisor and clients confidence in the sampler's work. This requirement allows for employees who may have not completed their degree to work in a cannabis testing laboratory with adequate training for this specific position provided by supervisory or managerial employees.

§5739. Records

Proposed section 5739 requires that all laboratory records described in this chapter shall be maintained in accordance with section 5037 of this division. Records related to cannabis shall be kept for a minimum of 7 years and shall be made available upon request by the Bureau. It is necessary to keep records for a minimum of 7 years because in the event of a safety recall and/or a trace-back or trace-forward investigation records related to cannabis may need to be referenced. Records pertaining to cannabis shall be kept for a minimum of

7 years as mandated by Business and Professional Code section 26160. To comply with statutory regulations the testing laboratory must make the data package available to the Bureau.

§ 5800. Right of Access

Proposed section 5800 provides the notice and authority under which Bureau staff and representatives may access the licensee's premises and property for purposes of inspection, audit, investigation, or review. Subsection (a) allows for the Bureau to enter onto any licensed premises, test any vehicles or equipment used in the licensee's commercial cannabis activity, test any cannabis goods, and to copy any materials, books or records of the licensee. Subsection (b) preserves the rights of licensees, and subsections (c) through (e) proscribe that such rights of access as provided in this section attach to any inspection, investigation, review, or audit, for which prior notice is not required, and which shall be conducted at any time the licensee is exercising privileges under the license, or as otherwise agreed. Subsection (f) provides that if Bureau representatives must enter the licensed premises, through another licensed premises, both licensees are subject to discipline if access is denied.

Proposed section 5800 is necessary to establish the licensing authorities' access rights as to inspections, investigations, audits, and reviews. Several provisions of law grant the licensing authorities these rights to access, including Business and Professions Code section 26160 and Government Code section 11180 et seq. Licensing authorities must have the ability to fully and immediately access licensed premises, equipment, materials, and records, used in the operation of a commercial cannabis business, in order to carry out their duties and responsibilities under MAUCRSA, including determining whether an applicant or licensee is in compliance with MAUCRSA and its implementing regulations, and also in ensuring the protection of the public as the highest priority. Full and immediate access will allow the Bureau's representatives to immediately access any violations or situations that are a danger to the public safety and health, and also allows the Bureau's representatives to access the licensed premises without allowing an opportunity for licensees to conceal or cover any deficiencies or violations, which may pose a risk to public health and safety.

§ 5801. Notice to Comply

Proposed section 5801 provides licensees an opportunity to correct a deficiency, without a monetary penalty or through formal disciplinary procedures, through a notice to comply that is issued by the Bureau upon an observable violation of MAUCRSA or implementing regulations. This section provides a licensee an opportunity to correct a deficiency or violation, that does not necessarily require issuance of a citation or imposition of disciplinary action.

Proposed section 5801 is necessary in providing a mechanism for the Bureau to engage with licensees in achieving compliance, without having to issue more formal actions, such as citations, or formal discipline, such as suspension, or revocation, and to ensure there is a proscribed method for issuing and responding to Notices to Comply.

§ 5802. Citations; Orders of Abatement; Administrative Fines

Proposed section 5802 provides the procedures for issuing citations that contain orders of abatement or administrative fines, or both, for violations of MAUCRSA or regulations adopted pursuant thereto. Subsections (a) and (b) provide the Bureau's authority to issue such citations, derived from Business and Professions Code sections 125.9 and in carrying out Business and Professions Code section 26011.5, in ensuring public safety and health as the highest priority. Citations may be issued to licensees or persons engaging in commercial cannabis activity without a license. Subsection (c) proscribes the method and format by which the Bureau's citations are to be issued, subsections (d) and (e) provide for how a fine is assessed and how failure to pay an assessed fine may affect license renewal. Subsection (f) indicates that nothing in the proposed subsection prevents the Bureau from filing an accusation to suspend or revoke a license where proper grounds exist. This provides notice to licensees that a citation, order of abatement, or fee does not preclude the Bureau from taking further action if deemed necessary.

This section is necessary to provide the framework for how licensees may respond to a citation, including providing licensees notice on how a failure to pay an administrative fine may affect their ability to renew a license.

§ 5803. Contesting Citations

Proposed section 5803 provides the procedures on how licensees can contest a citation, including the timelines for contesting a citation by requesting either, an informal conference with the Bureau, or an administrative hearing pursuant to Government Code section 11500 et seq. Subsections (a) and (b) provide the timeframe a licensee has to contest a citation, either within 30 days of service of the citation for an administrative hearing, or within 15 days of service, for an informal conference with the Bureau. Subsections (c) through (e) establish the procedure for the informal conference, which must be held within 15 days of the licensee's request, and that at the end of the informal conference, the Bureau may affirm, modify, or dismiss the citation, and provide the decision by writing, which will be deemed a final order. Subsection (f) clarifies the process for modifying a citation, fine, or order of abatement. In these cases, the citation, fine, or order of abatement is considered withdrawn and replaced with the modified version. This proposed subsection also clarifies that a hearing may be requested within 30 calendar days.

This section is necessary to effectuate any due process rights a licensee may have upon the issuance of a citation containing an order of abatement or an administrative fine. This section provides the licensee an opportunity to contest the citation through an informal conference whereby the licensee may present evidence and information before the Bureau for consideration of a modified citation, or in addition to the informal conference, to proceed with an administrative hearing on the citation, governed by the Administrative Procedures Act under Government Code section 11500 et seq.

§ 5804. Citation Compliance

Proposed section 5804 specifies the procedures for how a licensee may provide notice of compliance with an order of abatement issued pursuant to a citation. Subsection (a) specifies that the timeframe for complying can be extended for good cause, and provides how and when a cited licensee may request an extension to comply. Subsections (b) and (c) provide that failure to abate a violation within a citation, whether it is appealed or contested, is a violation itself, subject to further administrative or civil proceedings. This section is necessary to provide licensees and persons cited, the procedures for achieving citation compliance, including how and when a licensee can request an extension on the time to comply.

§ 5805. Minor Decoys

Proposed Section 5805 specifies the Bureau's authority for use of minor decoys, pursuant to Business and Professions Code section 26140, allowing the use of persons under 21 years of age to be used by peace officers in the enforcement of MAUCRSA, which prohibits the sale of cannabis goods to any individual under 21 years of age, unless the individual is over 18 years of age and qualifies as a medicinal cannabis patient or primary caregiver. Subsection (a) of section 5805 provides that peace officers may use such persons under 21 years of age to attempt to purchase cannabis goods, and can apprehend any person selling cannabis goods to minors, which is any individual under 21 years of age. Subsection (b) provides the minimum standards for the use of minor decoys, including that at the time of the operation, the decoy shall be less than 20 years of age, that the decoy must show his or her identification requested, and that the decoy shall answer truthfully any questions about his or her age, so that a licensee has a fair opportunity to determine if the minor decoy is under 21 years of age. The peace officer directing the minor decoy must make a reasonable attempt to enter the premises to have the minor decoy identify the alleged seller of cannabis goods.

This section is necessary to clarify and specify the use of minor decoys in enforcement, as provided for in MAUCRSA. The use of minor decoys by the Bureau and collaborating law enforcement agencies will be necessary to limit the sale of cannabis goods to minors as prohibited by law, and to carry out the duties and responsibilities of the licensing authorities in ensuring the protection of the public as the highest priority. This section provides the minimum standards in the use of minor decoys, to establish the legal framework and guidelines for such operations, which have been previously challenged. In general, the use of decoys to expose illegal activity does not in itself constitute entrapment. (*Provigo Corp. v. Alcoholic Beverage Control Appeals Bd.* (1994) 7 Cal.4th 561.) Such measures become invalid with the use of techniques that would induce otherwise law-abiding persons to commit a crime. (*Id.*, at 569.) The minimum standards under this section also establish procedures that do not unfairly or unlawfully entrap licensees in the sale of cannabis goods to minors.

§ 5806. Attire and Conduct

Proposed section 5806 provides for prohibited attire and conduct on licensed premises, mainly conduct that displays nudity or exploits sexual activity. This section is necessary to ensure that protection of the public is the highest priority, by limiting certain acts and behavior that have a historical correlation to crime. Permitting acts that are conducive to a sexually oriented business would pose a higher risk to public health and safety. While the commercialization and exploitation of sexual activity is not per se unlawful, the sexually oriented business enterprise and cannabis business enterprise have a commonality in that both industries involve cash-heavy transactions. Crime rates tend to be higher in areas where sexually oriented businesses are located, which would compound the safety risk to commercial cannabis businesses that also engage in sexually exploitative business practices. Clients, customers, and employees would also be exposed to an increased risk of such criminal activities.

§ 5807. Entertainers and Conduct

Proposed section 5807 specifies the nature of live entertainment that may be allowed on licensed premises. It prohibits any live entertainment that is sexually oriented or exploitative. This section, similar to proposed section 5806 is necessary to ensure that protection of the public is the highest priority, by limiting certain acts and behavior that have a statistical and historical correlation to crime. Permitting acts that are conducive to a sexually oriented business would pose a higher risk to public health and safety. While the commercialization and exploitation of sexual activity is not per se unlawful, the sexually oriented business enterprise and cannabis business enterprise have a commonality in that both industries involve cash-heavy transactions. Crime rates tend to be higher in areas where sexually oriented businesses are located, which would compound the safety risk to commercial cannabis businesses that also engage in sexually oriented or exploitative business practices. Clients, customers, and employees would also be exposed to an increased risk of such criminal activities.

§ 5808. Additional Grounds for Discipline

Proposed section 5808 provides additional grounds for discipline of either a licensee, or a person engaging in unlicensed activity, which are grounds in addition to section 26030 of the Business and Professions Code. Proposed subsection (a) provides that a licensee may be disciplined for failing to pay a fine imposed by the Bureau, or agreed to by the licensee. Subdivision (b) provides disciplinary grounds for failure to correct objectionable conditions on licensed premises, including adjacent areas. Proposed subsection (c) provides that a licensee may be disciplined for failing to correct objectional conditions on any public sidewalk abutting their premises, specifying that failing to correct objectional conditions includes failing to contact local law enforcement or failing to request any persons engaging in or causing objectional conditions to cease. Subsection (d) clarifies that even if the licensee corrects the objectionable conditions, the licensee continues to have an obligation to meet the requirements of proposed subsections (a) and (b) of this section. The proposed subsection also notifies the licensee that failure to meet the requirements may be ground for discipline.

Proposed subsection (e) provides grounds for discipline, a licensee permitting the illegal sale of a controlled substance or dangerous drug, and subsection (f) provides that a licensee can be disciplined for utilizing a specific solicitation scheme on the premises.

This section is necessary to carry out the mandate of the Bureau in ensuring the protection of the public as the highest priority. Failure to pay a fine imposed by the Bureau or agreed to by the licensee is a violation of rules and regulations that indicates non-compliance and requires disciplinary action. Civil Code section 3479 defines a nuisance as anything which is injurious to health, including, but not limited to, the illegal sale of controlled substances, anything indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property. This proposed section is necessary to prohibit activities that would be injurious to health or and around commercial cannabis businesses for which the licensee controls.

§ 5809. Disciplinary Actions

Proposed section 5809 provides the structure by which the Bureau takes disciplinary action against a licensee. Subsection (a) specifies the process of service for an accusation recommending disciplinary action against a licensee. Subsection (b) provides how a hearing on the accusation will be conducted, should the licensee request a hearing. Subsection (c) provides the Bureau's ultimate decision on the taking of disciplinary action subsequent to a hearing, including ordering the revocation of the license, outright suspension, or suspension on probationary restriction. Subsection (d) provides for how the Bureau and licensee may enter into a stipulation prior the conclusion of a hearing, which would effectively terminate the accusation. If the Bureau declines to accept the offer of a proposed settlement, it will not disqualify the Bureau from hearing evidence on the accusation and taking further action as authorized.

This section is necessary to provide the licensee guidance on the disciplinary process, and specifically on the licensee's appeal rights and hearing on the accusation, which are governed by the Administrative Procedures Act, under Government Code section 11500 et seq.

§ 5810. Interim Suspension

Proposed section 5810 provides for the ability of the Bureau to pursue an interim suspension order against a licensee, when continued operation of the licensee's business would endanger the public health, safety, or welfare. The section provides for instances when the Bureau may seek an interim suspension order after providing notice to the licensee, and instances when notice are not required prior to issuing an order of interim suspension, such as when it appears from the Bureau's petition and supporting documents that serious injury would result to the public before the matter can be heard on notice. The section also provides the timeframe for when the Bureau must provide a hearing on the petition, service of the notice of the hearing, and filing of the accusation.

This section is necessary in instances where continued operation of a licensee will adversely impact public health and safety. Since disciplinary procedures afford timeframes before

certain actions can be taken, a mechanism to take direct and more immediate action is necessary when circumstances require it.

§ 5811. Posting of Notice of Suspension

Proposed section 5811 requires that the licensee post on the licensed premises, a notice of suspension. Subsections (b) and (c) require the suspended licensee maintain certain size and dimensions of the posted notice, and prohibits the licensee from providing a reason for suspension on the posted notice other than the reason provided in the final decision suspending the license. Subsections (d) and (e) specify that the posting is to remain in place for the duration of the suspension, and if the posting is removed or rendered illegible, the licensee is required to contact the Bureau within a given amount of time. This section is necessary to provide transparency and notice to consumers and the public of disciplinary action, and limits the ability of the licensee to continue to engage in commercial cannabis activity when prohibited from doing so.

§ 5812. Posting of Notice of Revocation

Proposed section 5812 requires that the licensee post on the licensed premises, a notice of revocation. Subsections (b) and (c) require the revoked licensee maintain the posting for at least 15 days, and requires certain dimensions of the posted notice. Subsections (d), (e), and (f) specify that the posting is to remain in place for the duration of the suspension, and if the posting is removed, the licensee is required to contact the Bureau within a given amount of time. This section is necessary to provide notice to consumers and the public of revocation of a license, and prevent continued operations of a revoked license.

§ 5813. Enforcement Costs

Proposed section 5813 provides for the reimbursement of enforcement costs to the Bureau, by a licensee. Subsection (a) specifies that the Bureau may request an administrative law judge to direct a licensee found to have violated a provision of law, to pay a sum that does not exceed the reasonable cost of the investigation and enforcement of the case. Subsection (b) specifies that the Bureau may provide an actual certified copy of the costs, or a good faith estimate, which would include costs incurred up to the date of the hearing, and imposed by the Attorney General. Proposed subsection (c) clarifies that the administrative law judge shall make a proposed finding of reasonable costs of investigation and prosecution when requested. The proposed subsection also clarifies that the Bureau may reduce or eliminate the cost award, or remand to the administrative law judge if the proposed decision fails to make such a finding. Subsections (d) and (e) specify the Bureau's right to enforce the order in any appropriate forum, and provides that proof of the decision is conclusive proof of the validity of the order on payment and terms. Subsection (f) clarifies that the Bureau shall not renew or reinstate a license of any licensee who has failed to pay off all costs ordered under the proposed section, except in specific instances. This provides notice to the licensee that they will not be able to have a valid license if they do not comply with the requirements by paying the amount ordered. Subsection (g) specifies an exception to subsection (f). This subsection clarifies that the Bureau may conditionally renew or reinstate the license of a

licensee who demonstrates financial hardship and enters into an agreement with the Bureau for reimbursement. This allows more flexibility in allowing licensees to pay the costs owed under this section. Subsection (h) clarifies that this proposed section does not preclude the Bureau from including the recovery of costs of the investigation and enforcement of any case in any stipulated settlement. This section is necessary to specify the Bureau's authority to seek reimbursement of enforcement costs, and how and when the Bureau will seek these costs from a licensee.

§ 5814. Disciplinary Guidelines

Protection of the public is the highest priority of the Bureau, when taking regulatory and enforcement action. Proposed section 5814 provides the guidelines for disciplinary action taken by the Bureau against a licensee, including revocation, suspension, and probation. The Disciplinary Guidelines provide recommended penalties for specific violations of statutory or regulatory provisions under the jurisdiction of the Bureau, as well as suggested terms and conditions of probation.

Section I of the Disciplinary Guidelines (page 3) provides the public and licensees with a brief overview of the disciplinary process for licensees and how the Disciplinary Guidelines are to be used. The Disciplinary Guidelines are not fixed disciplinary standards to which the Bureau must adhere, but deviation is appropriate as the Bureau, in its sole discretion, may determine. The Disciplinary Guidelines are incorporated by reference as publication in the California Code of Regulations, as doing otherwise would be cumbersome, impractical, and unnecessary. The multi-page document serves as a reference to the users of the guideline, including Administrative Law Judges, attorneys, licensees, and other third parties involved in the disciplinary process. It does not directly pertain to general members of the public. Additionally, the Disciplinary Guidelines will be accessible through the Bureau's website, and available for review and copy at the Bureau's offices. This proposed Section I is necessary to clearly identify the most current version of the Disciplinary Guidelines, and establish the relevant purpose of the Disciplinary Guidelines and its accessibility, by addressing who is subject to the Disciplinary Guidelines, and how and when the Disciplinary Guidelines are to be used. This will be beneficial in eliminating any confusion on the users of the Disciplinary Guidelines.

Section II of the Disciplinary Guidelines (page 4) include factors that will be used in determining the appropriate penalty for disciplinary action, with the maximum penalty imposed being revocation of a license. The level of penalty, which can include suspension, a fine, probation, or a combination of these, can be determined by mitigating factors that will result in a lesser penalty, or aggravating factors, which will result in a higher penalty. The purpose of this proposed Section II is to provide a specific list of those factors that will be considered by the Bureau in imposing any penalty, so that a licensee is aware of what penalty may be imposed, and how they may address such a penalty when contesting or appealing any decision for disciplinary action. The factors to be considered, either in mitigation or aggravation of a penalty, include, the nature and severity of the act or offenses under consideration, the actual or potential harm to the public, actual or potential harm to any consumer, prior disciplinary record, number and/or variety of current violations, mitigating

evidence, rehabilitation evidence, compliance with conditions of sentence and/or court ordered probation for any criminal conviction, overall criminal record, time passed since the act or offenses occurred, and if applicable, evidence of expungement proceedings pursuant to Penal Code section 1203.4.

Consideration of the nature and severity of the act or offenses will allow each disciplinary action to be evaluated on a case-by-case basis. Violations may involve circumstances that are unique to each case, so a one-size-fits-all penalty would not be appropriate when imposing a fair and consistent penalty. Determining the nature and severity of an act or offense will be beneficial in accounting for these circumstances.

Actual or potential harm to the public or consumer is another factor to be considered when determining an appropriate penalty. This factor is important in consideration of a penalty, because the Bureau is tasked with protection of the public as its highest priority. Preventing actual or potential harm to the public or any consumer is the objective of the Bureau, and any penalty imposed must account for whether this objective has been breached by the licensee, through its acts or offenses.

Prior disciplinary record is another necessary factor to be considered because it will determine the appropriate level of penalty that will also help deter the licensee from engaging in similar conduct in the future. Existence of a prior disciplinary record may indicate that a higher level of penalty may be needed to deter the licensee from future violations, as previous disciplinary actions have been unsuccessful in doing so.

The number and/or variety of current violations is a necessary factor to impose a commensurate discipline, which will ensure fairness. Where the act or offenses involve a criminal offense, factors that will be considered include rehabilitation evidence, any expungements, time passed since the offenses occurred, or compliance with conditions of a sentence or court-ordered probation. This, along with the overall criminal record, will help determine the appropriate penalty, because it may show the likelihood of whether the licensee can comply with the terms and conditions of probation, and likelihood of repeating past violations. The licensee can also provide any mitigating evidence in support of a lesser penalty, all facts that may be relevant to a fair and consistent determination of penalty.

Section III of the Disciplinary Guidelines (pages 5 – 10) provides three tiers of disciplinary action, ranging from stayed revocation and suspension, to revocation of a license, and the calculation of minimum and maximum fine amounts pertaining to each violation. Representative violations for each tier are listed, with Tier 1 representative violations comprising of violations that are potentially harmful, Tier 2 representative violations comprising of violations with a serious potential for harm and involve greater risk and disregard for public safety, while Tier 3 representative violations are comprised of knowing or willful violations of law or regulations, and fraudulent acts relating to the licensee's business.

The tiered levels of discipline are necessary to ensure that the appropriate penalty is levied against commensurate violations. The Fine Formula is to be used where a fine is imposed as part of the disciplinary action, and provides for calculations based on a licensee's average

daily sale amount and the number of days suspended. The purpose of the Fine Formula is to provide notice of minimum and maximum fine amounts, that is a fair and consistent penalty amount commensurate to the scale of the licensee's business, which is calculated to penalize and deter continued violations of the law and regulations. This is necessary to ensure the protection of the public. A monetary penalty will also allow for a more tailored disciplinary action, effectively designed to meet its intended purpose.

Section IV of the Disciplinary Guidelines (pages 10-13) includes the introductory language for the terms and conditions of probation, and provides the standard conditions of probation, which includes requirements and processes for submitting reports during probation, reporting in person when required, complying with all state and local laws, maintaining valid licenses, displaying and posting signs related to probation, license surrender and violations of probation. Terms and conditions of probation will be imposed when staying a disciplinary order, such as revocation or suspension of a license. The probationer may continue to exercise the privileges of licensure, while under probation, as a means of disciplinary action that is fair.

Under proposed paragraph 1, the respondent probationer is required to obey all state and local laws, and to submit the required fingerprint forms and fees. The purpose of this requirement is to ensure that the probationer is obeying all state and local laws, which shows that the probationer is fit for continued licensure. The fingerprint requirements will allow the Bureau to effectively monitor compliance with this condition of probation. Probationers are required to submit written reports during the probation period that detail the probationer's compliance with the conditions of probation, as required under proposed paragraph 2. This provision will help the Bureau to ensure that the probationer is complying with the conditions of probation, and is fit for continued licensure.

The Bureau will also require under proposed paragraph 3, that when necessary, the probationer must report in person for any interviews or meetings. This is to ensure that the probationer is able to comply with the conditions of probation, and when necessary to effectively and directly communicate with Bureau staff regarding any issues arising during their probation period. Under proposed paragraph 4, the probationer is to fully comply with the conditions of probation, and shall timely inform the Bureau of any address change. This is to ensure that the Bureau has the ability to immediately and directly communicate with the probationer, and monitor the probationer's presence in California. Allowing the probationer 15 days to provide notice of an address change is reasonable, given the methods by which the probationer is to provide notice.

The probationer is also required to post appropriate signage during any period of suspension, under proposed paragraph 5, which is necessary to prevent the probationer from engaging in any prohibited activities, such as exercise of the suspended license, and to advise the public of such prohibition. The probationer is also required to circulate a notice of probation to all employees, which is necessary to ensure that the employees do not unknowingly exercise any privileges of a license that is prohibited or limited during probation, or while it is suspended.

Proposed paragraph 6 requires the probationer to maintain a valid license during the probationary period. This is necessary to ensure that the probationer does not allow the license to lapse, and circumvents the purpose of serving a probationary period. Proposed paragraph 7 provides that the probationer is responsible to costs associated with its investigation and enforcement, which is a restatement of Business and Professions Code section 26031, subdivision (d), and restated here for clarity.

Proposed paragraph 8 allows the probationer to surrender their license if they are unable to satisfy the conditions of probation, or ceases business, however such surrender will be at the discretion of the Bureau and may be considered a disciplinary action. This is necessary to ensure that probationers abide and comply with the conditions of probation, while providing probationers with the ability to choose to no longer retain the privileges of licensure, or to no longer engage in commercial cannabis activity.

Proposed paragraph 9 provides probationers with notice that any violation of probation may set aside the order of probation, and impose the stayed discipline of revocation or suspension. This is necessary to ensure that probationers are aware of the consequences of probation violations, and to deter any such violations.

Section V of the Disciplinary Guidelines (pages 12-13) provides template introductory language to be placed in all orders, providing the parties to a disciplinary action, especially the Administrative Law Judge, with standard introductory language that is applicable to all cases and licensees, and contains information as to the penalty imposed and severability of the conditions contained in the order. This section provides uniformity in discipline among licensees on probation, and also provides that optional terms and conditions may be imposed on probation.

The Disciplinary Guidelines are also necessary to ensure the highest level of public and consumer protection, by establishing guidelines for those involved in the administrative disciplinary process, such as licensees, Administrative Law Judges, Deputy Attorney Generals, or other interested parties. It provides a framework for protecting the public through disciplinary actions, clearly and concisely communicates the disciplinary action for given violations, provides notice of possible consequences for such violations, and facilitates the rehabilitation of probationers in a fair and consistent manner.

§ 5815. Emergency Decision and Order

This proposed section provides the authority and process by which the Bureau may issue an emergency decision and order, pursuant to Government Code section 11460.10 et seq. Because protection of the public is the highest priority under the Bureau's statutory mandates, it is necessary that the Bureau have all available tools to administer and enforce the provisions of MAUCRSA and related laws, to ensure public health, safety, and welfare. The public and members of the cannabis industry will benefit from the Bureau's ability to take immediate action to ensure their health and safety, by limiting exposure to unsafe cannabis goods, unsafe conditions at a licensed premises, and other harms created by illegal activity.

Emergency decisions are provided for under the Administrative Procedures Act (APA), commencing at Government Code section 11460.10. Under the APA, an agency, such as the Bureau, may issue an emergency decision for temporary, interim relief when there is an immediate danger to public health, safety, and welfare, if the agency has adopted regulations providing for its use. Consistent with the APA, this proposed section specifies when the Bureau may issue an emergency decision and orders, and the procedures for before and after issuance of an order.

Specifically, pursuant to the APA, the agency's implementing regulation must set forth, the specific circumstances in which an emergency decision may be issued, the nature of the temporary relief that the agency may order, and the procedures that will be available before and after issuance of an emergency order.

Proposed subsection (a) specifies the circumstances by which the Bureau may issue an emergency decision and order for temporary, interim relief to prevent or avoid immediate danger to the public health, safety, and welfare. These include, when the Bureau has information that cannabis goods at a licensed premises have a reasonable probability of causing serious adverse health consequences or death, to prevent the transfer of contaminated or illegal cannabis goods, when the Bureau may have knowledge of conditions at a licensed premises that presents an immediate risk to worker or public health and safety, to prevent illegal diversion of cannabis goods or other criminal activity at the licensed premises, to prevent the destruction of evidence related to illegal activity or a violation of MAUCRSA, and to prevent misrepresentation to the public that could result in the sale of untested cannabis goods. This proposed subsection establishes some of the circumstances for which the Bureau anticipates needing immediate action, necessary to protect public health and safety, because they present the most potential harm to consumers and the public. This subsection is necessary to comply with the APA requirement that an agency's implementing regulation set forth the specific circumstances in which an emergency decision may be issued. The Bureau determined that the specific circumstances enumerated in this subsection are necessary for the preservation of public health, safety, and welfare.

Proposed subsection (b) provides for the types of temporary, interim relief that the Bureau may issue, including a suspension or administrative hold. Such a suspension or administrative hold order could include, the temporary suspension of a license, an order to segregate or isolate specific cannabis goods, an order prohibiting the movement of cannabis goods to or from the premises, an order prohibiting the sale of specific cannabis goods, and an order prohibiting the destruction of specific cannabis goods. This proposed subsection captures the activities and circumstances for which suspension or a hold, is necessary to protect public health and safety. Preventing harm to the public, due to exposure of unsafe cannabis goods or criminal activity related to cannabis goods, may require immediate action, and is best achieved through means of a suspension of commercial cannabis activity or an administrative hold on cannabis goods, or both. A licensee placed on temporary suspension will not be able to sell or provide unsafe or dangerous cannabis goods to consumers and the public, and cannabis goods placed on administrative hold cannot be sold or transferred to consumers and the public. This subsection is necessary to comply with the APA requirement that an agency's implementing regulation set forth the nature of the

temporary relief that the agency may order. The Bureau determined that the temporary relief enumerated in this subsection would be necessary to preserve the public health, safety, and welfare if one of the circumstances enumerated in subsection (a) were to occur.

As required by the APA, under Government Code section 11460.50, proposed subsection (c) specifies the contents of the emergency decision and order, to include a brief explanation of the factual and legal basis of the emergency decision that justifies the determination that immediate action is necessary, and the specific actions ordered. The proposed subsection also provides for the effective date of an emergency decision and order, which shall be upon issuance, or as otherwise stated in the decision and order. This proposed subsection restates in part, the statutory requirements, and is necessary to convey what the specific actions ordered are, and the justification for such orders so that the person to whom the order is directed, can cease any prohibited activity, or otherwise comply with the emergency decision and order. It is important that the orders specify the actions to be taken, so as not to diminish the efficacy of the emergency decision and order. Justification of the determination will also help to provide clarification as to any order.

Proposed subsection (d) provides for processes relating to an administrative hold. An administrative hold prohibiting activity related to specified cannabis goods requires the Bureau to provide notice that includes a description of the cannabis goods subject to the hold, and to identify the cannabis goods in the track and trace system. Proposed subsection (e) requires a licensee subject to an administrative hold to, within 24 hours of notice, segregate and preserve the designated cannabis goods. While on administrative hold, the cannabis goods cannot be transferred in any manner, and may be voluntarily surrendered. This subsection does allow a microbusiness licensee to continue cultivation of designated cannabis which is necessary because unlike other activities that can simply be stopped, cultivation involves live plants which require continued care. This proposed subsection is necessary, to establish and provide notice of the respective duties of both the Bureau and the person subject to an administrative hold, upon the issuance of such an emergency decision and order, and to limit exposure of potentially dangerous and harmful cannabis goods and preserve cannabis goods that may be subject to review or investigation. This is also necessary to ensure that a proper review and investigation may be carried out by the Bureau in enforcing any provision of law.

Proposed subsection (f) specifies when a temporary suspension is ordered, and requires the Bureau to specify in the order that the licensee must immediately cease conducting all commercial cannabis activities, unless otherwise specified in the order. This proposed subsection is necessary to ensure public health and safety through cessation of potentially dangerous or criminal activity, and to clarify that a suspension encompasses all commercial cannabis activities, which must cease, unless exceptions are provided for in the order. The clarification will help to avoid any continued commercial cannabis activity upon a suspension, through sufficient notice to the licensee. Proposed subsection (g) clarifies that cultivation may continue upon a temporary suspension order, for a microbusiness, and if harvested, the cannabis is to be placed in separate batches. This proposed subsection is necessary to ensure that cannabis goods are preserved during the suspension period, and not destroyed. This is also beneficial to ensure integrity in the review and investigatory process.

Proposed subsection (h) provides for notice and hearing procedures upon issuance of the emergency decision and order, and provides for notice and an opportunity to be heard prior to issuance or effective date, if practicable. Such notice and hearing may be oral or written and may be through telephone, personal service, mail, facsimile transmission, electronic mail, or other electronic means, as permitted. Proposed subsection (h)(3) provides for who may receive such notice, and proposed subsections (h)(4) through (h)(6) specify procedures for the hearing, conducted as an informal conference, which may be requested in writing within three business days of receipt of the notice, and heard within 5 business days.

Following the hearing, the Bureau has five business days to affirm, modify, or set aside the emergency decision and order. The provisions for notice and the hearing to be oral or written, by telephone, facsimile transmission or other electronic means, is a restatement of the APA, and included here for clarification. The APA also provides, under Government Code section 11460.20, subdivision (b)(3), that an agency may prescribe procedures before and after the issuance of the emergency decision, that are more protective than what is provided in the APA. This proposed subsection is necessary to specify the rights and duties of the licensee and Bureau for notice and a hearing, and affords protections beyond what is provided for in the APA.

The APA, under Government Code section 11460.60 requires an agency issuing an emergency decision and order to commence adjudicative proceedings to resolve the underlying issue giving rise to the temporary relief, within 10 days after issuance of the emergency decision and order. This proposed subsection is a restatement of the law, necessary for clarification and to establish a comprehensive regulatory framework for emergency decisions and orders issued by the Bureau. Proposed subsections (j) and (k) provide for further review of the emergency decision and order, by means of an appeal to the Cannabis Control Appeals Panel after adjudicative proceedings, or through judicial review under Code of Civil Procedure section 1094.5, at any time. Judicial review in this manner is a restatement of the APA and included for clarification. The Cannabis Control Appeals Panel is established under Business and Professions Code section 26043 et seq., for any appeal by a person aggrieved by a Bureau decision affecting licensure, such as suspension, revocation, assessment of a fine, or other imposition of a condition on a license. These subsections are necessary to provide the licensee direction and clarification on the appeals process they are afforded under this proposed section.

§ 5900. Eligibility

Proposed section 5900 sets out the initial criteria and conditions for selection for funding, which is that only a public university in California can be selected for research funding, and that such funding is subject to availability and an amount of ten million dollars (\$10,000,000) disbursed annually. This is a restatement of Revenue and Taxation Code section 34019, subdivision (b), and is restated here for clarity, as to who these provisions apply to, and how.

§ 5901. Request for Proposals

Proposed section 5901 establishes how the Bureau will notify eligible recipients of available funds for research. The Bureau will provide notification through a Request for

Proposal (RFP), which will include information on the available funding for research, criteria for the review and selection process, any requirements for the proposal, any restrictions or priorities imposed upon the use of the funds, the governing statutes and regulations for the research project, and the contact information for Bureau staff that can provide further information regarding the submission of proposals. This is necessary to ensure that potential fund recipients are aware of when funds are available for research projects, and how they may apply for funding. This also follows the requirements under Public Contracts Code section 10344, which sets out the requirements for requests for proposals. This will help to ensure that there is an eligible pool of applicants for selection, and that the research required under Revenue and Taxation Code section 34019 will be met.

§ 5902. Selection Process and Criteria

Proposed section 5902 establishes the selection process and criteria, which requires that an applicant timely submit proposals for review, and only submit one application for a given research project. This is to ensure that there is consistency and fairness in the selection process, and that projects are timely funded. The criteria for selection will also include the extent to which the proposed project is designed to meet the statutory objectives, and whether it is feasible, as determined by its timeline for completion and budget details. Qualifications of staff, and other criteria will also be assessed in making the selection. This proposed section is necessary in order to ensure that the funding will be disbursed and spent on only those projects that have a likelihood of successfully researching and addressing the issues in Revenue and Taxation Code section 34019, subdivision (b). These issues largely address the public health and safety issues, and economic impacts, stemming from the legalization of adult-use cannabis in California, and is important in better understanding an industry that has largely been underground, and a product that has not been widely researched.

§ 5903. Release of Funds

Proposed section 5903 establishes the guidelines for the release of funds, including when they can be disbursed, and any conditions of use. This will let the recipients know what they must do in order to receive and keep the funds that have been granted to them through the selection process. Disbursements of funds can only occur after an agreement has been signed, as also required under the Public Contracts Code, and that such disbursement is a single disbursement, in order to align with Revenue and Taxation Code section 34019. The recipient is also prohibited from using these funds in the purchase of any equipment, unless the Bureau has approved such purchase and is provided receipts for the purchase. Any funds that are not used during the research project prior to completion, will be forfeited. This section is necessary to ensure that funding is aligned with the objectives of the statute, and that taxpayer money is being efficiently and properly used.

§ 5904. Reports and Records

Proposed section 5904 requires proper documentation and retention of the research project data, and reports of the research project. Recipients must provide regular performance reports on the status of their research project, as well as publish annual reports to the

public, as required under Revenue and Taxation Code section 34019, subdivision (b). This proposed section is necessary to ensure that funding is aligned with the objectives of the statute, recipients are in compliance with the grant agreement, and that taxpayer money is being efficiently and properly used. This will also help the Bureau to develop an efficient system for selection of recipients for funding, in understanding the research process.

Incorporation by Reference:

The following documents are incorporated into the regulations by reference:

US Food and Drug Administration's *Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition, April 2015.

US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, 2nd Edition, April 2015.

Bureau of Cannabis Control Disciplinary Guidelines July 2018.

The following forms are incorporated into the regulations by reference:

Transportation Procedures, Form BCC-LIC-015 (New 7/18)

Inventory Procedures, Form BCC-LIC-016 (New 7/18)

Non-Laboratory Quality Control Procedures. Form BCC-LIC-017 (New 7/18)

Security Procedures, Form BCC-LIC-018 (New 7/18)

Cannabis Waste Management Procedures, Form BCC-LIC-019 (New 7/18)

Delivery Procedures, Form BCC-LIC-020 (New 7/18)

Sampling – Standard Operating Procedures, Form BCC-LIC-021 (New 7/18)

Sample Preparation – Standard Operating Procedures, Form BCC-LIC-022 (New 7/18)

Test Methods – Standard Operating Procedures, Form BCC-LIC-023 (New 7/18)

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

The following documents were relied on for this rulemaking process:

1. 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).
2. 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).
3. Analytical 360, *Moisture Analysis* <<http://analytical360.com/cannabis-analysis-laboratory/interpreting-your-laboratory-data, 2015>> (as of Mar. 28, 2017).
4. 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).
5. 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).
6. 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).
7. 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).
8. Breier, J., Hard Car Security, LLC, Safety, Transparency and Accountability for the transportation of Cannabis Products and Cash. (Oct. 2016).
9. 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).

- 10. 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.
- 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 8, 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 9, 2017.
- 13. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Hearing Transcripts on Proposed Medical Cannabis Regulations. Hearing Date June 13, 2017.
- 14. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Hearing Transcripts on Proposed Testing Laboratory Regulations. Hearing Date June 20, 2017.
- 15. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Public Comments on Proposed Medical Cannabis Regulations.
- 16. Bureau of Cannabis Control formerly known as “Bureau of Medical Cannabis Regulation” Public Comments on Proposed Testing Laboratory Regulations.
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ALTERNATIVES CONSIDERED

In accordance with Government Code section 11346.5, subdivision (a)(13), the Bureau must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less

burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Bureau invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

In considering the proposed regulations, the Bureau considered a lower-cost alternative and a higher-security alternative. The proposed regulations impose a 50-pound maximum batch size for testing. The proposed regulations also require the use of an enclosed vehicle for deliveries of cannabis and allow for one retailer employee to make deliveries on their own. Additionally, the proposed regulations require that licensees maintain security cameras in specific locations with at least a 1280 x 720 resolution at a minimum of 15 frames per second. The proposed regulations also require that video footage be stored for at least 90 days. The proposed regulations require that cannabis goods be rendered unrecognizable and unusable prior to disposal and that cannabis waste be disposed of by licensed waste haulers. The proposed regulations require that retailers only sell cannabis goods between the hours of 6 a.m. and 10 p.m.

The lower cost alternative would remove the maximum batch size for testing. The lower cost alternative would also allow for delivery using a bicycle, motorcycle, or scooter in addition to enclosed vehicles. Like the proposed regulations, the lower cost alternative would allow for one employee to make deliveries by themselves. The lower cost alternative does not have any security-video requirements. The lower cost alternatives have no waste storage and disposal requirements. The lower cost alternative also does not restrict the hours that a retailer may sell cannabis goods.

The higher-security alternative would lower the maximum batch testing size to 10 pounds. The higher-security alternative would also require the use of enclosed vehicles for delivery, but would require that at least 2 employees make deliveries together. Additionally, the higher security alternative would require security cameras to be placed at specific locations. Under the higher-security alternative would require that the cameras record at least at a resolution of 1280 x 1024 at a minimum of 20 frames per second and that the footage be stored for at least 90 days. The higher-security alternative includes more stringent waste cannabis waste disposal requirements. The higher-security alternative also requires that prior to disposal, cannabis waste be disguised by blending with solid waste or soil, the waste be weighed and labeled with a bill of lading, and quarantined in a dedicated area on camera for 72 hours prior to disposal. Like the proposed regulations, the higher-security alternative requires that retailers only sell cannabis goods between the hours of 6 a.m. and 10 p.m.

The proposed regulations are expected to increase the total compliance cost by \$408 per pound. The proposed regulations are expected to result in an increase in the cannabis

industry's revenue by \$695 million with an increase in quantity sold by 33,765 pounds when compared to the non-regulated baseline. The lower-cost alternative is expected to increase compliance costs by \$350 per pound, or \$58 per pound less than the proposed regulations. The lower-cost alternative is expected to result in an increase in the cannabis industry's revenue by \$665 million with an increase in quantity sold by 43,755 pounds when compared to the non-regulated baseline. The higher-security alternative is expected to increase compliance costs by \$744 per pound or \$336 per pound more than the proposed regulations. The higher-security alternative is expected to result in an increase in the cannabis industry's revenue by \$641 million with a decrease in quantity sold by 57,549 pounds when compared to the non-regulated baseline.

The lower-cost alternative was not chosen because the additional safety and security obtained from the proposed regulations are important enough to warrant the additional cost. Adequately monitoring the premises of licensees, preventing theft during deliveries, and ensuring adequate and accurate testing are all very important in maintaining the safety and security of the public. Additionally, the lower-cost alternative is expected to result in smaller industry revenue than the proposed regulations. Therefore, the Bureau elected to proceed with the proposed regulations over the lower-cost alternative.

The higher-security alternative was not chosen because the higher costs of this alternative are not warranted by the marginal increase in safety and security. Having at least 2 delivery employees make deliveries does decrease the risk of theft while making deliveries. However, this decrease in theft can be achieved through other methods without having to employ an additional employee. For example, if a delivery employee ensures that the vehicle they use for deliveries has all the required security features, and the employee does not leave cannabis goods in the vehicle unattended, the risk of theft can be decreased without the need for an additional employee. The smaller maximum batch limit of 10 pounds as compared to the 50-pound limit in the proposed regulations is expected to greatly increase cost, but provide very little benefit in terms of more accurate testing. Also, the higher-security alternative is expected to have a smaller increase in industry revenue when compared to the proposed regulation. Therefore, the Bureau has elected to proceed with the proposed regulations over the higher-security alternative.

Economic Costs and Benefits of Proposed Bureau of Cannabis Control Regulations for the Implementation of the Medicinal and Adult Use Cannabis Regulation and Safety Act (MAUCRSA)

Standardized Regulatory Impact Analysis

Prepared for the California Bureau of Cannabis Control
by the University of California Agricultural Issues Center
18 April 2018

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Economic Costs and Benefits of Proposed Bureau of Cannabis Control Regulations for the Implementation of the Medicinal and Adult Use Cannabis Regulation and Safety Act (MAUCRSA)

Standardized Regulatory Impact Analysis (SRIA)

The Bureau of Cannabis Control (“Bureau”), formerly named the Bureau of Marijuana Control, Bureau of Medical Cannabis Regulation, and Bureau of Medical Marijuana Regulation, will be proposing final regulations to implement the Medicinal and Adult Use Cannabis Regulation and Safety Act (MAUCRSA), which combines and amends the statutes previously propagated in the Medical Cannabis Regulation and Safety Act of 2015 (MCRSA) and Adult Use of Marijuana Act of 2016 (AUMA). MAUCRSA re-establishes the Bureau as the state’s licensing and enforcement authority for the distribution, transportation, testing, and dispensing of cannabis in California, including those activities conducted by operations licensed as microbusinesses.

This Standardized Regulatory Impact Analysis is submitted for the purpose of evaluating the benefits and costs of the regulations proposed by the Bureau, many of which went into effect in preliminary form as emergency regulations on December 7, 2017. The University of California Agricultural Issues Center (AIC) assessed the costs and benefits of the Bureau’s proposed regulations and two alternative sets of regulations.

On some issues, MAUCRSA provided detailed regulatory specifications that the proposed regulations implement precisely. On other issues, MAUCRSA provided broader guidance about the regulations. This SRIA considers the full package of proposed regulations, including those that implement precise statutory requirements. AIC gathered detailed cost, price, quantity, and other information to assess the impact of the proposed regulations on the industry and on the state. The results of this analysis are presented in this SRIA with background information and details provided in the Appendix.

AIC's analysis of the cannabis industry in California was conducted on both the medicinal and adult-use cannabis segments in the state, both of which have been taxed and regulated according to the statutory requirements of MAUCRSA and the regulations proposed by the Bureau. In this document, we use the term "adult use" to refer to non-medicinal cannabis sales, and we use the term "illegal" to refer both (1) to the segment of current and future cannabis sales in California that are unlawful under the MAUCRSA or current California criminal code, and (2) to the segment of past cannabis sales that were previously unlawful under whatever statutes were in force at the time of such sales, including AUMA, MCRSA, and earlier versions of California criminal code.

After outlining statutory authority, this SRIA summarizes the scope of analysis and outlines AIC's approach to the calculations of economic impacts. A key feature of the approach is defining a baseline against which to measure the economic impacts of the proposed regulations. These direct economic impacts are characterized in terms of effects on prices, quantities, revenues and taxes.

After measuring economic effects of the proposed regulations on the California cannabis industry, AIC used a standard economy-wide model (IMPLAN) to project ripple effects on the California economy more broadly. The SRIA outlines findings in terms of employment, impacts on businesses, potential influence on broad indicators of benefits and costs, and government revenues.

Finally, in addition to the benefits, costs and related impacts of the proposed regulations, AIC evaluated the benefits and costs of two alternatives: an alternative to represent a lower-cost package of regulations and an alternative to represent a higher-security package of regulations.

1. Statutory authority

The set of statutes collectively known as the Medical Cannabis Regulation and Safety Act (MCRSA), which became effective in 2015, established the Bureau within the California Department of Consumer Affairs and assigned to the Bureau the responsibility of creating

and administering a licensing and enforcement structure for the distribution, transportation, testing, and retail sale of medicinal cannabis in California.

The set of statutes collectively known as the Control, Tax and Regulate Adult Use of Marijuana Act (AUMA), which became effective after the passage of Proposition 64 in the California general election of November 2016, legalized the sale and regulation of adult use cannabis to adults 21 and over in California, and established a system for regulating and taxing the adult-use cannabis segment. On June 27, 2017, California Senate Bill 94 (SB 94) amended, reconciled, and consolidated MCRSA and AUMA into a single act: The Medicinal and Adult Use Cannabis Regulation and Safety Act (MAUCRSA).

Under Government Code section 11346.3, a California state agency proposing a “major regulation,” which Government Code section 11342.548 defines as “any proposed adoption, amendment, or repeal of a regulation subject to review by the Office of Administrative Law that will have an economic impact on California business enterprises and individuals in an amount exceeding fifty million dollars (\$50,000,000), as estimated by the agency,” is required to prepare a Standardized Regulatory Impact Analysis (SRIA) to be submitted to the state Department of Finance for review and comment before the regulations are noticed to the public.

The first requirement of a SRIA is that it must verify that the regulation under review meets the definition of “major regulation” under Government Code § 11342.548. The regulations adopted by the Department of Finance further define the threshold as \$50 million in either costs or benefits occurring within one year of full implementation of the proposed regulations.

AIC calculations showed that these proposed regulations met the definition of “major regulation,” as explained in Section 7 below. In our approach to this and other determinations to be made in the SRIA, AIC relied on guidance from the 2015 joint report from the Office of Administrative Law and Department of Finance, which clarifies the interpretation of

Government Code section 11346.3 with respect to SRIA content, purpose, and the “major regulation” determination.¹³⁸

2. Nature and scope of regulatory impacts considered

The economic calculations and simulations reported below proceeded in three steps. First, we empirically assessed the 2017 situation for cannabis in California as it stood near the end of 2017.

Second, we projected the impacts on the medicinal and illegal cannabis market segments of the launch of adult-use sale and taxation of all legal cannabis. This step establishes a relevant base for the regulatory analysis. It provides the baseline against which the proposed regulations may be measured. We call it the “Taxation Baseline.” Evaluating this baseline before evaluating the impact of regulations allows analysts to consider each of these two sets of effects independently.

The third step, and central focus of the SRIA, is to calculate and simulate the impact of the proposed Bureau regulations on the medicinal and adult-use cannabis segments separately from the effects of taxation. We called this final market scenario “Proposed Regulations.” Under MAUCRSA, a cannabis business may apply for a single microbusiness license that allows the business to operate under a single license in multiple segments: cultivation, level 1 manufacturing, distribution, and retail. If a microbusiness has both medicinal and adult use cannabis, then two microbusiness licenses would be needed. Operations using a microbusiness license are allowed cultivation in an area of less than 10,000 square feet and may only conduct level 1 manufacturing, which refers to making cannabis products using nonvolatile solvents, or no solvents. The microbusiness must conduct three of the four potential activities and all activities must be on the same premises. Note there are no size restrictions on distribution or retailing in the microbusiness license provisions.

¹³⁸ November 1, 2015, report by the Directors of the Office of Administrative Law and Department of Finance to the Chair of the Senate Committee on Governmental Organization and the Chair of the Assembly Committee on Governmental Organization, SB 617 and Finance Regulations appended.

The Bureau has responsibility to issue licenses to cannabis microbusinesses. However, the cultivation and manufacturing activities of microbusinesses must meet the same provisions in the associated regulations covering other license types (as issued by other agencies) for those activities. The state and local cultivation and manufacturing taxes and regulatory costs have already been included in the economic analyses of cultivation and manufacturing done for the SRIA of the California Department of Food and Agriculture or the California Department of Public Health, along with their analyses of cultivation or manufacturing activities under other licenses.

The distribution and retail activities of microbusiness license holders are analyzed in this SRIA. To avoid double counting, we do not include impacts of the cultivation regulations or the manufacturing regulations that cover microbusinesses. That is, this SRIA treats the cultivation and manufacturing conducted under microbusiness licenses in the same way that it treats those activities when conducted under other license types.

The license type for event organizers does not allow those organizers to act as distributors or retailers. Any cannabis sold at event requires a license for that activity, either a retail or microbusiness license. We include the quantities, revenues, and impacts of regulations related to cannabis sold at events in our analysis of the distribution and retail activities.

3. Approach to economic modeling

Measuring the economic impact of a regulation is contingent on estimating relevant baseline market prices, quantities, revenues, taxes, and related aggregates that would occur in the absence of the regulation. The creation of such a baseline is often not as simple as assuming current conditions continue to apply in the absence of the regulations, even when data about market conditions are readily available.

The economic data and modeling underlying this SRIA are unusually complex for two reasons: (1) the unavailability of much relevant government or other public data and unavailability of much relevant banking, accounting, or other private data; and (2) the necessity of developing a counter-factual projected baseline that enabled the analysis to estimate the separate effects of taxation and adult-use legalization from the impacts of the proposed regulations.

First, there are no official government data sources on output, prices, jobs, or other economic aggregates for the industry to which the proposed regulations on medicinal cannabis apply, and official tax collections reflect a minority of operating businesses. Because much of the industry to which the proposed regulations apply has long been prohibited by Federal law, normal industry data have not been reported in standard authoritative Federal sources.

Moreover, businesses have not reported their financial results in standard ways. In many cases, businesses have been operating with cash, outside of the normal banking system, in a quasi-legal, quasi-regulated manner. Furthermore, the closely related adult-use segment has been illegal even under state law. Finally, illegal prices and quantities are even more difficult to estimate, with a high degree of price dispersion, uncertainty, and rapidly changing market conditions.

The lack of reliable authoritative public or private data required AIC to develop estimates of data that would have been readily available for most other industries. For instance, we collected price data from about 2,500 medicinal cannabis retailers in California. Estimates of economic aggregates and relationships provided below are approximations based on the best available information as of December 2017.

Second, as noted in Section 2, MAUCRSA legalizes, regulates, and imposes taxes on both legal medicinal and legal adult-use cannabis. The joint launch of these two regulatory systems, which took place with licenses beginning to be effective January 1, 2018, created legal sales in two cannabis segments: medicinal cannabis and adult-use cannabis. When fully in place, such a dual-segment system will enable many buyers who had previously been buying in the medicinal segment to shift purchases to the adult-use segment. However, there is a financial benefit for some buyers in the medicinal segment for whom tax savings more than offsets the annual cost of obtaining a medicinal recommendation from a physician and a county-issued medicinal identification card. Cannabis buyers will realize financial savings from remaining in the medicinal segment if they purchase sufficient quantities of cannabis annually such that

their savings of approximately 8% in avoiding the sales and use tax exceeds their approximately \$100-per-year cost of obtaining a medicinal recommendation and ID card. There are also a handful of legal advantages to the medicinal system, which are discussed in Section 5.

In addition to Bureau regulations, many regulations related to the cultivation of cannabis, taxation of cannabis leaving the cultivation site, and regulation of the manufacturing of cannabis products commenced at the same time. The impact of these regulations also must be considered separately from the Bureau regulations that are the focus of this SRIA.

In order to isolate the impact of the proposed regulations from the impact of taxation and the legalization of adult-use sale in the relevant economic situation and context, AIC modeled and simulated the implications and effects of a hypothetical scenario in an adult-use cannabis retail market exists side-by-side with the legal medicinal cannabis segment. In this scenario, both adult-use and medicinal are taxed, including local and state taxes, but neither is regulated. We call this the “Taxation Baseline.”

These effects created the baseline against which we simulated the impacts of regulations. We then analyzed the impacts of the proposed regulations on the medicinal and adult-use cannabis segments in the context of the (hypothetical) cannabis industry with the baseline of taxation and legalized adult-use sale in place.

Let us illustrate the magnitude of the issue more concretely and foreshadow the estimates presented below. Based on our best assessment, in 2017 the California medicinal cannabis segment without adult-use sales was on pace for aggregate pre-tax revenue of about \$2.5 billion. Without yet considering the implications of the proposed regulations, but taking into account the legalization of the cultivation and sale of adult-use cannabis; state regulations implemented for cultivation and manufacturing; local regulations implemented for all segments of the cannabis industry; and the taxation of all legal cannabis, our economic calculations suggest that revenue in the medicinal cannabis segment will decline, while the new adult-use segment will grow to be slightly larger than the medicinal segment in before-tax retail spending. Thus, the proposed Bureau regulations are likely to apply to an overall legal

cannabis segment with retail revenue without counting state excise and sales taxes of about \$5 billion.

Projecting the effects of taxes or regulations on a market requires the specification of supply and demand response parameters. These are often expressed as elasticities—a percentage change in quantity with respect to a percentage change in price or other causal factor. In this case, key estimates and assumptions include how responsive demand for cannabis overall is to prices and how responsive demand for cannabis in each segment is to relative prices in those segments. Simulation also requires evidence and assumptions about shifts in demand affecting each segment. On the supply side, we used assumptions about how responsive supply in each segment was to relative prices across segments. Evidence and assumptions about shifts in costs were required as well.

In summary, in order to isolate the impact of the proposed regulations, our procedure was to incorporate the changes to the marketplace step by step. First, based on conditions for the 2017 cannabis market, we simulated the economic effects of legal adult-use sale, taxation and regulations by all government entities, both state and local, other than the Bureau. Next, we incorporated the impact of the proposed Bureau regulations into the model and solved for economic aggregates. Finally, we assessed the impact of the proposed regulations by comparing the Taxation Baseline with a scenario that adds the effects of Bureau regulations on top of that baseline.

In constructing separate estimates for the medicinal and adult-use segments, we evaluated the differences between the local and state regulations, including sales tax differences, differences in possession limits, and other axes of variation in legal allowances and criminal penalties. The principal differences are articulated in Section 5.

Our estimates in this SRIA use the tools of “equilibrium displacement,” which compares hypothetical equilibrium situations that incorporate the supply and demand shifts caused by state and local regulations, taxes, tourism, and other supply and demand effects we expect to occur. This method of comparing equilibrium situations that are different because of imposition of policies and regulations is a standard economic approach to modeling and is often the most

straightforward approach when considering alternatives that have not yet occurred. Of course, all methods of economic modeling have their advantages and drawbacks.

One of the drawbacks of equilibrium displacement modeling is that it compares two static equilibria and does not develop quantitative estimates for the adjustment paths of prices, quantities and other aggregates that evolve over time. The equilibrium approach does allow detailed estimates for a period applicable after initial market flux has settled out of the system and generates concrete estimates that meet the statutory requirements for a SRIA and are compatible with the IMPLAN model for presenting broad economic impacts and ripple effects.

The mandate of a SRIA is to estimate the economic impact in the 12 months after the regulations go into effect. The equilibrium estimates developed and reported in this SRIA assume that the regulatory changes are internalized into prices and consumer and producer behavior.

The projected impacts presented in this SRIA are applicable to a one-year period after the regulations are fully implemented and markets have adjusted to those regulations. We do not specify a particular set of dates to which this analysis applies, because the time period until full implementation and adjustment is still uncertain. It is possible that the California cannabis market will display the volatility and disarray common in immature markets in the midst of structural change for several months, or even years, after regulations are implemented but are still short of full implementation. All of our estimates should be interpreted with this in mind.

4. Overview of data collection and initial market conditions

In constructing initial estimates of prices and quantities in the California cannabis market that applied in 2017, AIC drew upon a variety of sources, including our own AIC retail cannabis price survey, which was conducted by AIC researchers in October 2016 through November 2017 (details and results are in Appendix Chapter 4); third-party longitudinal retail and wholesale price surveys (Appendix Chapters 3 and 5); an AIC meta-analysis of published scientific journal articles, white papers, and government reports; and confidential AIC interviews with market experts and industry participants (Appendix Chapters 3 and 5). The appendix includes a complete list of references to documents cited and reviewed.

AIC started from estimates of the revenue of California medicinal cannabis retailers in 2017. There are no official or widely accepted industry estimates of the size of the pre-legalization-and-regulation (medicinal) cannabis industry in either revenue or quantity terms. AIC estimated that in 2017 there was about \$2.5 billion of total annual sales revenue (not including sales taxes) being collected in the medicinal cannabis segment.

We developed that \$2.5 billion revenue estimate as follows: The California Department of Tax and Fee Administration (CDTFA, formerly known as the Board of Equalization) has estimated sales tax revenue from medicinal cannabis retailers was approximately \$60 million in 2015. No full year data were available for 2016. The statewide average tax rate is about 8.3% and that the rate of tax compliance was estimated at about one third.

Using an effective tax rate of about 3% (0.083 times 0.33), \$60 million in sales tax receipts implies industry revenue of about \$2.1 billion. This estimate is within the range of other published estimates. For more detail, see discussion and tables in Appendix Chapter 5. We estimate quantity to be growing at a 10% annual rate between 2016 and 2017.

Using data from the AIC survey of retail prices and other sources, we estimated the November 2017 market price of retail medicinal cannabis in California to be about \$3,600 per flower-equivalent pound. By flower-equivalent pound, we simply mean a unit of cannabis sold at retail that is equivalent to one pound of dried flowers for retail sales.

More specifically, the data from the AIC survey (Appendix Chapter 4) provide information on a variety of prices in November 2017 from a large sample of more than 2600 cannabis retailers from every part of California. AIC collected data on prices of two package sizes for dried flowers and on prices of non-flower products. Unfortunately, no data on quantities transacted were available. AIC therefore used auxiliary information from interviews with industry participants and industry publications to develop weighted averages of product prices. AIC focused on the cannabis dried flower prices to create a flower-equivalent average price.

With the price of \$3,600 per pound, the estimated California 2017 retail sales revenue of about \$2.5 billion implied an annual retail quantity of flower-equivalent units of approximately 700,000 pounds of medicinal cannabis sales, before adult use cannabis was available from legal retail markets.

AIC estimated that in 2017, about 25% of total cannabis by volume (i.e. flower-equivalent pounds) that was sold in California was sold in the legal medicinal segment, and the remaining 75% was sold in the illegal segment. This estimate is based on the literature reviewed in Appendix Chapter 5 and interviews with industry participants. We estimate that in 2017, aggregate annual sales in the illegal segment, where price was lower, were \$5.0 billion, and total cannabis retail sales in California were about \$7.5 billion.

5. Baseline market conditions with adult-use sale, taxation and non-Bureau regulations

For about two decades, the only cannabis legally available for sale in California has been medicinal cannabis, which, according to the Brown Guidelines, can be sold only to California state residents over the age of 18 with doctors' recommendations and for the use of those between ages 12 and 18 with parental guidance.

A doctor's recommendation has been relatively easy to acquire; for example, receiving a recommendation did not require an in-person medical examination and could be accomplished with a short visit to one of many websites. Under the requirements of MAUCRSA, an in-person examination is required, but it is hard to estimate how much effect this will have on the cost of obtaining a medicinal recommendation and the number of permit holders.

Consumers over the age of 21 in the medicinal cannabis segment can readily shift to the adult-use segment, which would not require the added step of obtaining a doctor's recommendation. On the other hand, sales and use taxes in the adult-use segment that are exempted for medicinal cannabis may offset this savings for those who purchase substantial quantities in a year. Whether consumers end up in the medicinal or adult-use segments of the legal market depends in part on how much the price differential between legal and illegal

cannabis grows due to taxes. With taxation, more consumers who would otherwise have entered or remained in one of the legal segments may now shift to the illegal segment.

In Washington State, the quantity purchased in the medicinal segment fell by one-third in the first year after the legal adult-use cannabis system took effect, and by more subsequently. Colorado, which has had a legal medicinal cannabis industry since 2001 and began taxing and regulating adult-use cannabis in 2015, is a more apt comparison. But there are many important differences between the Colorado and California taxes, regulations, and other market characteristics. See Appendix Chapter 10 for details and references to comparative literature.

As mentioned above, there are several reasons that a significant quantity of cannabis may remain in the medicinal segment. Remaining buyers in the medicinal segment may include:

- Buyers who wish to possess more than one ounce of dried flower (medicinal consumers can possess up to eight ounces)
- Buyers who want to buy edibles more potent than those allowed for adult-use purchase under the regulations
- Buyers who wish to possess open containers or opened and resealed containers of cannabis in the passenger area of a vehicle (adult-use cannabis must have its original seal and can only be transported in the trunk of a vehicle)
- Buyers who are between 18 and 20 years of age
- Buyers for whom a medicinal retail establishment is more convenient
- Buyers for whom a medicinal recommendation is important to their personal acceptance of cannabis use (say, for personal values, family relationships, or job rules)

Some buyers may find the legislated sales-tax exemption to be cost effective (saving consumers an average of 8.3% per transaction); however, eligibility requires obtaining a state-authorized county identification card, which we estimate costs about \$50 per year

plus the time investment required to obtain the card.¹³⁹ On the other hand, some consumers may be dissuaded from obtaining the card because they do not want to register their name with the government as a cannabis user.

Although the state-authorized county identification card is not necessary for medicinal cannabis buyers to enter a medicinal cannabis retail location or purchase medicinal cannabis, the language of MAUCRSA implies that the state-authorized county identification card will be necessary to receive the sales and use tax exemption.

Current state records indicate that relatively few medicinal cannabis buyers (less than 7,000 annually for the past few years) have obtained a state-authorized identification card.¹⁴⁰ The AIC analysis suggested that eligible buyers that wish to buy in the legal segments and who spend less than about \$1,500 per year on cannabis, about four ounces, could realize cost savings by switching from the medicinal segment to the adult-use segment. Aside from the legal advantages mentioned above, we identified no economic reasons that would restrain most low-volume buyers from switching.

There are also no apparent supply-chain advantages for the medicinal cannabis segment that might translate to lower consumer prices for medicinal cannabis relative to adult-use cannabis. Cultivators and distributors are permitted under MAUCRSA to produce both medicinal and adult-use cannabis in the same production facilities, so switching will also be fluid from a production and distribution standpoint. Advertising, vertical integration, and other restrictions are also imposed equally on the medicinal and adult-use segments.

AIC analysis indicated that the opening of the market for adult-use cannabis and associated taxation will cause demand and supply in the existing cannabis market to change in several important ways that are relevant to the impact of cannabis regulations. First we specify three demand-side effects, and then we explain supply-side effects, the biggest of which is the combined effects of state and local taxation.

¹³⁹ <https://www.boe.ca.gov/pdf/l481.pdf>

¹⁴⁰ <https://www.cdph.ca.gov/programs/MMP/Documents/MMPCounty%20Card%20Count%2012-16.pdf>

5.1 Demand-side effects resulting from adult-use legalization, taxation, and non-Bureau regulations

Demand effect (A): Some current demand in the legal medicinal cannabis segment may shift to the newly legal adult-use segment due to the lower annual transaction costs. Adult-use cannabis purchase does not require an annual doctor's recommendation, which is costly for buyers of medicinal cannabis. Costs are likely to be \$50 or more per year plus the cost of time and inconvenience. An in-person doctor's visit is now required by MAUCRSA. This demand effect is described in more depth in Appendix Chapters 5 and 7.

Demand effect (B): We project that with a legal adult-use segment available, demand currently in the illegal adult-use segment will move to the legal adult-use segment to avoid the inconvenience, stigma, and legal risks of buying from an unlicensed seller with whom there is no legal recourse. The adult-use segment gains most of this formerly illegal quantity, and the medicinal segment gains as well. Part of the demand shift is in response to tracking and security advantages of legal cannabis as opposed to illegal cannabis.

Adult-use and medicinal cannabis each also lose in quantity demanded from what would otherwise occur because of higher prices due to taxation and non-Bureau regulatory costs. In our models, the demand effect B is also represented as a reduction of demand within the current illegal segment offset in total cannabis purchase by an increase in the newly-legal adult-use segment by the roughly the same magnitude. This demand effect is described in more depth in Appendix Chapters 5 and 7.

Demand effect (C): The third demand-side effect attributable to taxation, non-Bureau regulation and adult-use legalization is a growth in the aggregate consumer demand for legal cannabis among consumers who were not previously in the California cannabis market at all. AIC modeled this as an increase in the demand for legal adult-use cannabis of about 5% of total cannabis sold in the period before the Taxation Baseline.

We expect this demand increase for two reasons. The first is new demand created by the opening of the cannabis market to consumers in the state who have had interest in the product but have avoided it until now. Some of these potential consumers did not want to get

a medicinal cannabis recommendation when they felt they had no medical condition that warranted use. Moreover, potential consumers may have avoided the illegal market because of inconvenience, legal risk, or unwillingness to participate in illegal drug activity because of moral concerns or social stigma. Finally, an increase in publicity and advertising may attract purchasers who had not previously entered the market.

The second component of the outward demand shift resulting from adult-use legalization is new demand created by the opening of the cannabis market to California's out-of-state leisure and business visitors. There are more than 260 million visits to California from residents of other places per year. These visitors spend more than \$122 billion in California.¹⁴¹ A significant portion of this spending is on leisure goods and services. For instance, tourists have been estimated to spend \$7.2 billion per year on wine in California.¹⁴²

Demand for new forms of leisure spending by tourists and other visitors to California is potentially large. Given that adult-use cannabis remains illegal in most other states, California's legalized adult-use industry may attract some new visitors whose primary reason for visiting the state is cannabis tourism, as has been observed in Colorado. This effect is discussed in the context of tourism survey data from Colorado in Appendix Chapter 10 and included in the model in Appendix Chapter 7.

Some researchers have reported a dramatic impact of cannabis tourism in Colorado—a state that, like California, already has a booming tourist industry—while others have reported only modest gains. One source of uncertainty with respect to tourist demand lies in the known negative self-reporting bias in cannabis consumption surveys, a bias that may be stronger amongst tourists who have little incentive to admit to using drugs that are illegal in their home states.

Self-reported use rates, which are cited in many studies and which we draw on to project market size and compare California data with that in other states are associated with uncertainties beyond predicting tourist demand. Self-reported use rates have been known to

¹⁴¹ <http://industry.visitcalifornia.com/Find-Research/California-Statistics-Trends/>

¹⁴² Estimates of California wine tourism at <http://www.discovercaliforniawines.com/media-trade/statistics/>.

jump dramatically when states legalize adult-use cannabis (29% in Colorado, for instance), and it is not known to what extent this effect can be attributed to actual increased use rather than a diminished negative self-reporting bias as cannabis becomes less of a taboo in the state.

5.2 Supply-side effects of adult-use sale and taxation

5.2.1 Adult-use sale. As cannabis is moved more into the mainstream of the economy through legalization of adult-use cannabis, suppliers have better access to capital, technology and management. With legalization of the sale of adult-use cannabis in 2018, legal sellers have a lower chance of loss from forfeiture and lower probabilities of criminal prosecution. Recent data have shown that the cannabis industry has unusually high costs compared to production and marketing of other agricultural products, and that many of these costs, including risk premiums, can be attributed to the illegality of adult-use cannabis sales prior to November 2016. This is reflected in the large differences (large compared with non-cannabis industry norms) that AIC and other industry observers have documented between costs per unit reported by businesses and receipts per unit at each stage in production, processing, distribution, and retailing of both medicinal and illegal cannabis.

In recent years, especially after the passage of AUMA in 2016, lower operating costs and lower risk premiums are being observed as new capital comes into the marketplace. At the same time, as long as the uncertainties of Federal law remain in place, businesses in the cannabis industry will continue to face unique challenges even when cannabis is taxed and regulated on a state level. For instance, it does not appear that businesses will have access to the normal banking system even after taxation and regulation. New challenges also face the industry as it prepares for the greater levels of inspection and oversight mandated by MAUCRSA. We therefore assume a 10% reduction in the business costs of selling both adult-use and medicinal cannabis in the Taxation Baseline.

Basic operating costs and the cost of labor in cannabis businesses will likely fall as the cannabis industry becomes more mainstream, attracts investment from legal sources, attracts better management, and improves practices throughout the supply chain. These lower direct costs are more than offset by higher regulatory costs and taxes. Such regulatory costs and taxes are

implemented by the state for cultivators and manufacturers and local regulations and taxes are applied throughout the supply chain. More information on these impacts is found in Appendix Chapters 3, 5, 6, and 7.

5.2.2 Taxation. The new system of taxes on cannabis is likely to have substantial impact on quantities sold in the legal segments. The Taxation Baseline assumes full compliance with state and local taxes and regulations. The state excise tax of 15% is based on an estimate of retail revenue that is collected at the distributor level. Cannabis is also subject to California's usual sales and use tax of 7.25% plus local jurisdiction taxes that average about one percent. (As noted above, sales to certain buyers in the medicinal segment are exempt from the sales and use tax.) The sales and use tax is expected to be fully enforced on the legal cannabis market, which has not occurred in the past.

In constructing the Taxation Baseline, we incorporate our estimate of local cannabis retail taxes (see Section 5.2.3) as well as the state and local cultivation taxes and regulatory costs imposed on cultivators and manufacturers. These include the regulations and licensing fees for cultivation proposed by the CalCannabis division of the California Department of Food & Agriculture (CDFA) as well as local cultivation taxes and fees (see section 5.2.4), and the regulations and licensing fees for manufacturing by the California Department of Public Health (CDPH) as well as local manufacturing taxes and fees (see Section 5.2.5).

5.2.3 Local cannabis retail taxes. The landscape of local taxation continues to change rapidly. Hundreds of municipal and county meetings were held throughout 2017 to determine the structure and details of legal cannabis tax and regulation policies. Such decisions are still under consideration in many places. Local policies have sometimes been changed, repealed, or reversed. AIC obtained data from CannaRegs, a leading provider of legal information and analysis for the cannabis industry, from which we constructed a snapshot of the local tax situation as of June 2017, including sales and use taxes and local cannabis taxes.

In order to estimate local taxes, we began with California's 7.25% state sales and use tax and add a weighted average of local sales and use tax rates around California. The local weighted average sales and use tax at the cash register is 1.05%, extrapolating from a population-

weighted stratified random sample of jurisdictions across the state covering areas including 50% of the state's population. We therefore use a total weighted average sales and use tax across all 540 jurisdictions at 8.3% (7.25 plus 1.05). Per MAUCRSA, this tax is assessed on the adult-use segment, but only partially on the medicinal segment.

In order to estimate state-wide average local cannabis-specific retail tax rates, we assessed 50 adult-use retail cannabis tax rates and 51 medicinal retail cannabis tax rates from throughout California. We found a local cannabis-specific retail tax (added on top of state and local sales and use taxes, state excise taxes, etc.) averaging 9.55% for medicinal cannabis (51 observations) and 10.13% for adult-use cannabis (50 observations). (Similar data found for cultivation the medians were \$25 per square foot for cultivation and 10% for local cannabis taxes on both medicinal and adult use.)

Most jurisdictions that have determined local cannabis retail taxes have set the same tax rate on medicinal and adult-use cannabis. A minority of jurisdictions have set lower rates for or exempted medicinal cannabis from local taxation, resulting in a slightly lower state-wide average for medicinal cannabis taxes of 7.8% compared to 8.2% for adult-use cannabis.

We assumed full compliance after taxation and adult-use legalization.

5.2.4 Costs of cultivation taxes and regulations. To estimate cultivation taxes and regulatory costs, we rely on the estimates of ERA Economics, which prepared the SRIA for CDFA. This includes \$148 per pound (in dried flower equivalent) in state cultivation taxes; local taxes and fees of \$108 to \$219, depending on grow type (for a weighted average estimate of \$128); and other regulatory costs of \$41 to \$91 per pound, depending on grow type (with a weighted average across the types of \$50, recognizing the importance of greenhouse and indoor cannabis in the legal and regulated cannabis market). These costs include state license fees, track and trace, labor, pesticide, labeling, and other compliance. AIC estimated the total cost of these state regulations plus state and local taxes and fees of \$326 per pound, included in the Taxation Baseline. For details on these calculations, see Appendix Section 5.2.4.

5.2.5 Costs of manufacturing taxes and regulations. For manufacturing regulatory costs and local taxes, we rely on the estimates of the Humboldt State University team that prepared the SRIA for CDPH. We estimated the total cost per pound of \$95 per pound, including local taxes, state and local license fees, labeling requirements, track and trace, and other costs. For details, see Appendix Section 5.2.5.

The total of cultivation and manufacturing taxes and regulations is thus $(\$326 + \$95) = \$421$.

The changes in demand, costs, and taxes resulting in the “Taxation Baseline”, based on our simulation of the California cannabis market, can be summarized as follows. Once these market changes are incorporated, before regulations are applied, the legal adult-use segment will have about 26% of total quantity (about 711,000 pounds with a full tax-inclusive price of \$4,698 per pound), the medicinal segment will have about 21% of the total quantity (about 594,000 pounds with a price of \$4,439 per pound), and the unregulated illegal segment will have about 53% of the overall quantity (about 1,473,000 pounds with a price of \$2,636 per pound). The total quantity is about 2.78 million pounds (all measured in dried-flower equivalent). These calculations are detailed in Appendix Chapter 8, Tables 8.1a–8.3e.

Our regulatory impact analysis evaluated the impact of Bureau regulations relative to this hypothetical Taxation Baseline.

6. Overall market impact of the proposed regulations

AIC created the Taxation Baseline as described in order to identify and isolate the expected economic effects of the proposed cannabis regulations. Our simulations control for legal sales in the adult-use segment, taxation and non-Bureau regulations in order to isolate the economic impact of the Bureau's proposed regulations from the impact of the other recent changes to the California cannabis marketplace.

6.1 Drivers of economic impacts of proposed regulations

The economic effects of the proposed Bureau regulations on market prices and quantities derive from four sources. Two sources are on the cost and supply side: (1a) the direct costs imposed on the industry by the regulations compared with the Taxation Baseline, and (1b) reductions in retailer costs as regulations create a more transparent and reliable business environment. Two sources are on the demand side: (2a) less access to the legal cannabis segments because of restricted hours of operation of retail stores and delivery services, and (2b) an increase in consumer willingness to pay for the tested and regulated product compared with the situation without regulations but with taxation and adult-use sale.

First, the Bureau regulations impose direct costs on the cannabis industry. Details about components of the industry costs of complying with the proposed regulations are described below in Section 12. In that section, compliance costs of the proposed regulations are compared with compliance costs of two alternatives: an alternative package of lower-cost options and an alternative of higher-security and higher-cost options. The costs of compliance, and the data and calculations underlying them, are discussed in more detail in Appendix Chapter 6.

Overall, we found that the proposed regulations (compared to no regulations) add approximately \$408 per pound of marketable dried-flower equivalent in direct operating costs. Most of the addition to costs, about \$257 per pound, is due to the added costs of cannabis testing. In addition to regulations that have direct quantifiable costs, we model impacts of proposed regulations, which are based directly on the MAUCRSA.

The adult-use and medicinal regulations and costs are similar, and restrictions limiting vertical integration (i.e. participating in several stages from cultivation through retailing) are relatively minor for both medicinal and adult-use segments. In simulation models, AIC specified that the direct cost increase for both the adult-use and medicinal segments caused by the proposed regulations was approximately 11% of the initial value of \$3,600 per flower-equivalent pound. This was calculated as \$408/\$3,600.

Regulations that require detailed track-and-trace systems, security cameras, recordkeeping, and similar measures have a side effect of causing the distribution and retail services to move more thoroughly into mainstream business channels. These regulations thus help make the business more attractive to mainstream sources of labor, management, and capital. While it is hard to quantify the associated cost reductions, to recognize these impacts, we attribute a 2% reduction in operating costs to the overall regulatory environment. This partly offsets the direct cost increases caused by the regulations themselves.

Proposed Bureau regulation details are in Section 12 where they are compared to alternatives. The four main categories are (a) Bureau license fees which are estimated to cost \$44 per pound; (b) added distribution regulation costs, especially child-resistant packaging, which are estimated to cost \$48 per pound; (c) regulations on retail delivery, which are expected to cost \$10 per pound; and (d) retail compliance, including waste storage and disposal, video surveillance archive, and other MAUCRSA-mandated regulations, which are estimated to cost \$49 per pound. The total of these four categories is \$151 per pound.

The second broad set of economic effects of the proposed Bureau regulations is on the demand side. Restrictions on the operating hours of retail establishments and delivery services require that these businesses only operated between 6am and 10pm. Prior to this restriction, many medicinal cannabis retailers operated much later in the evening or even 24 hours per day, depending on their own business decisions and local restrictions. AIC research suggested that as of December 2017, there were more than 100 retailers in the state open 24 hours per day.

In December 2017, AIC surveyed 82 cannabis retailers from both northern and southern California by telephone and found that 63% were open after 10pm and 26% were open after midnight. Based on this survey we expect that a 10pm closing hour would reduce business hours by 13%, but we have no strong evidence of the share of daily quantities purchased during those hours.

Consumer responses to restricted hours are complex and fall into broad categories:

- (1) Some demand would shift to earlier hours. We would expect buyers who purchase large package sizes for their monthly use, for example, would continue to buy from their preferred source and shift to earlier in the day.
- (2) Other buyers that had less flexibility over time would not purchase cannabis at all, and shift their demand to some other product (say alcohol) that is available during the late evening hours when legal cannabis is unavailable.
- (3) Some demand would shift to the unlicensed or illegal cannabis segment, which is not limited by hours of operation.

It is hard to gauge the relative importance of these responses. In our simulations we assume that demand is reduced, for both segments of legal cannabis, by 2% and demand for illegal cannabis is increased by 1.5% due to the hours restrictions. This assumption implies that much of the quantity purchased during the hours where legal operation is no longer available shifts to available hours and remains in the legal segment. One reason for that response is that buyers with flexibility across segments and with easy access to the illegal segment are likely to have already chosen this lower priced option. Furthermore, as with other products, a high proportion of cannabis quantities are likely to be purchased by consumers who buy their weekly or monthly supply in large purchases to take advantage of volume discounts and this behavior indicates a degree of advanced planning. This is an additional source of uncertainty in our projections.

The largest demand impact is that increase in consumer willingness to pay for legal cannabis that has more security, traceability, labeling information, and intensive product testing. In the

AIC simulation, the increase in willingness to pay modeled as equivalent to an increase of 7% in willingness to pay compared with the situation without regulation but with taxation and adult-use legalization. This impact is converted to an equivalent shift in the quantity demanded at a given price using the own price elasticity of demand.

Most of the demand shift towards regulated and tested cannabis is from the illegal cannabis segment, so that segment experiences a reduction in willingness to pay by 6%. Some of the demand shift may also be from new entrants to the cannabis market who value a safe, secure and tested product. We discuss increased willingness to pay for government regulations on product traceability, testing and labeling with reference to some of the relevant literature in Appendix Chapters 5, 6, 7, and 8.

Margins of potential error include projections of prices and quantities and similar aggregates. The number of companies in each part of the industry and their distributions by size or location are especially uncertain. This is not only because of the lack of reliable data on the industry and the lack of direct comparability between California and other legal cannabis states, but also because of the unpredictable path of regulation, adoption, compliance, and common practices. All the effects will be even more difficult to project in the first months after full implementation, when compliance is still in flux and enforcement efforts are still not yet fully in place.

The data and assumptions used in simulations are in Table 1. These indicate the starting point for developing the Taxation Baseline and the economic impacts of Bureau proposed regulations that are applied to the Taxation Baseline. The initial quantities, prices and tax rates are those that apply in the hypothetical situation with both adult use and medicinal cannabis, but with none of the other features of the Taxation baseline incorporated. We assume initial quantity is 2.6 million pounds, price is \$3,600 per pound and tax paid is 2.5%. These are related to but are distinct from estimates for 2017, when adult use retailing was still not operational and the 700,000 pounds of adult use was largely in the medicinal and illegal categories.

TABLE 1. SUMMARY OF IMPORTANT DATA AND PARAMETERS FOR ESTABLISHING THE TAXATION BASELINE AND THE SIMULATION OF IMPACTS OF BUREAU REGULATIONS

| VALUE | <i>Medicinal</i> | <i>Adult use</i> | <i>Illegal</i> |
|---|------------------|------------------|----------------|
| INITIAL QUANTITIES (TOTAL FLOWER-EQUIVALENT LBS) | 600,000 | 700,000 | 1,300,000 |
| INITIAL RETAIL PRICES (PER FLOWER-EQUIVALENT LB) | \$3,600 | \$3,600 | \$2,340 |
| INITIAL EFFECTIVE TAX RATE | 2.5% | 2.5% | 0% |
| OWN PRICE SUPPLY ELASTICITIES ¹ | 5 | 5 | 5 |
| ELASTICITY OF SUBSTITUTION IN DEMAND ¹ | 5 | 2 | 2 |
| CONDITIONAL EXPENDITURE ELASTICITIES ¹ | 1 | 1 | 1 |
| OWN PRICE ELASTICITY OF DEMAND, EACH SEGMENT ¹ | -2.5 | -2.6 | -1.3 |
| DEMAND ELASTICITY, ALL CANNABIS COMBINED ¹ | -0.2 | -0.2 | -0.2 |
| INCOME ELASTICITY ¹ | 1.0 | 1.0 | 1.0 |
| STATE CULTIVATION TAXES (PER LB) | \$148 | \$148 | \$0 |
| LOCAL CULTIVATION TAXES (PER LB) | \$128 | \$128 | \$0 |
| CULTIVATION REGULATORY COMPLIANCE (PER LB) | \$50 | \$50 | \$0 |
| MANUFACTURING TAXES & COMPLIANCE (PER LB) | \$95 | \$95 | \$0 |
| EXCISE TAX RATE | 15% | 15% | 0% |
| SALES TAX RATE | 2.1% | 8.3% | 0% |
| LOCAL PERCENTAGE TAXES AND FEES | 7.8% | 8.2% | 0% |
| LOCAL PERCENTAGE TAXES ON TESTING REVENUE | 4.9% | 4.9% | 0% |
| COST INCREASE, TESTING REGULATIONS (PER LB, INCLUDING LOST INVENTORY) | \$257 | \$257 | \$0 |
| COST INCREASE, OTHER BUREAU REGULATIONS (PER LB) | \$151 | \$151 | \$0 |
| DEMAND SHIFTS (QUANTITY) FROM LEGALIZATION | 0% | 30% | 0% |
| COST SHIFTS DUE TO LEGALIZATION | -10% | -10% | 10% |
| COST SHIFTS DUE TO REGULATIONS | -2% | -2% | 0% |
| WILLINGNESS TO PAY SHIFTS FROM REGULATION & TESTING | 6% | 6% | -6% |

| | | | |
|--|-----|-----|------|
| DEMAND SHIFTS FROM HOURS LIMITS | -2% | -2% | 1.5% |
|--|-----|-----|------|

¹ Unit-less elasticity parameters.

6.2 Economic impacts on price, quantity, revenue and tax

Summary results of economic impacts of the proposed regulations are reported in three tables of this section. (Detailed estimates of market prices, quantities, revenues and taxes are reported in Appendix Chapter 8.)

In each of these three tables, column 1 lists variables of interest: Retail price to buyers, quantity, total revenue, and various tax revenues from each of the categories of taxes imposed by the state government and local governments. The final row shows retail revenue net of tax payments. Note that taxes do not include costs of complying with state and local government regulations. Those costs are built into the supply and demand structure and are instrumental in determining prices and quantities.

Table 2a presents simulated outcomes for the medicinal cannabis segment. Column 2 labeled “Taxation Baseline,” presents simulated values for estimates of prices, quantities, revenues, and taxes for medicinal cannabis, with legalization, taxation and non-Bureau regulation applied to both adult-use and medicinal sales, but without the Bureau’s regulations in place. Column 3, “Taxation Plus Bureau Regulations,” reports prices, quantities, revenues, and taxes with the proposed Bureau regulations imposed on the Taxation Baseline. Finally, Column 4, “Difference,” shows the impact of regulations as measured by the difference between the Taxation Baseline and taxation plus Bureau regulations.

In Table 2a, the Taxation Baseline has a retail price of \$4,439 per pound for medicinal cannabis with 594,319 pounds sold (in dried flower equivalent pounds). Total revenue is projected to be \$2.638 billion, which includes six categories of taxes paid to state and local authorities. Total tax collections are \$690 million so revenue net of tax payments is \$1.948 billion. As discussed above, sales tax revenues are low for medicinal cannabis because we assumed that three quarters of the cannabis sold in this segment would qualify for the sale tax and use deductions.

The third column of Table 2a shows the results for medicinal cannabis under the situation of the Taxation Plus Bureau Regulations scenario. Retail price is now \$4,841 per pound, or \$402 higher, as shown in the fourth column, to reflect the complex impacts of regulations that raise costs but also have value to buyers. Despite the higher retail price, the quantity sold in the medicinal segment rises to 615,699 pounds, more than 21,000 pounds above the quantity with the Taxation Baseline. Tax payments and revenue are also higher with the Bureau regulations in place because the taxes are tied to revenues and quantities, both of which are higher. Retail revenue net of tax payments rises by \$268 million to \$2.216 billion, which is not enough to cover the direct costs of testing and other regulations, implying that companies use the regulation environment to achieve further cost economies.

Table 2a. Medicinal Cannabis: Impacts of Bureau regulations on prices, quantities, revenues, and taxes compared to the Taxation Baseline

| <i>Variable</i> | <i>Taxation Baseline</i> | <i>Taxation Plus Bureau Regulations</i> | <i>Difference</i> |
|---|--------------------------|---|--------------------|
| Retail full price to buyers (\$/lb.) | \$4,439 ¹ | \$4,841 ¹ | \$402 ¹ |
| Quantity (lbs.) | 594,319 | 615,699 | 21,380 |
| | | (\$ millions) | |
| Total Revenue | \$2,638 | \$2,981 | \$343 |
| State cultivation tax revenue | \$88 | \$91 | \$3 |
| State excise tax revenue (15% of base) | \$317 | \$358 | \$41 |
| Sales tax, state revenue (1.8% average) | \$39 | \$44 | \$5 |
| Sales tax, local revenue (.03%) | \$6 | \$6 | \$0 |
| Local cannabis tax (7.8% of base) | \$165 | \$186 | \$21 |
| Local cultivation tax | \$76 | \$79 | \$3 |
| State tax revenue | \$444 | \$493 | \$49 |
| Local tax revenue | \$246 | \$271 | \$25 |
| Tax revenue | \$690 | \$764 | \$74 |
| Revenue without tax | \$1,948 | \$2,216 | \$268 |

Source: AIC simulations and calculations.

¹ Averages, not totals.

Notes: Pounds are in dried flower equivalents. Rounding affects column sums.

Table 2b follows the same structure as Table 2a. In column 2, the simulated Taxation Baseline for adult-use cannabis shows that the retail price is estimated to be \$4,698. The market quantity is 711,264 pounds and total revenue is \$3.341 billion, which includes taxes paid. The various taxes are again listed by category. Total tax revenue is now simulated to be \$997 million and revenue net of taxes is \$2.345 billion.

The third column of Table 2b shows the simulated results when Bureau regulations are implemented on top of the Taxation Baseline. Price and quantity both rise, with the price impact including the cost of the regulations as well as the other supply and demand responses. Quantity rises by 12,385 pounds. Total revenue rises by \$352 million. All the various categories of taxes rise and total tax revenue rises by \$87 million to \$1.084 billion. Revenue net of taxes rises by \$265 million or about 11% with the Bureau regulations compared to the Taxation Baseline.

Table 2c includes the simulated results for the combination of both the medicinal and the adult-use cannabis segments. The numerical columns include the summation of the numbers reported in Tables 2a and 2b. The exception is that the price row includes the weighted average of the prices in the first two tables.

With the Bureau regulations in place total cannabis sold in these two segments is projected to be about 1.34 million pounds, about 2.6% higher than under the baseline. Cannabis revenue is higher by about \$695 million to \$6.674 billion. About \$1.85 billion of this amount is tax revenue (\$162 million above the baseline) for a net-of-tax revenue of about \$4.825 billion.

Table 2b. Adult-Use Cannabis: Impacts of Bureau regulations on prices, quantities, revenues, and taxes compared to the Taxation Baseline

| Variable | <i>Taxation Baseline</i> | <i>Taxation Plus Bureau Regulations</i> | <i>Difference</i> |
|--|--------------------------|---|--------------------|
| Retail full price to buyers (\$/lb.) | \$4,698 ¹ | \$5,104 ¹ | \$406 ¹ |
| Quantity (lbs.) | 711,264 | 723,649 | 12,385 |
| | | (\$ millions) | |
| Total Revenue | \$3,341 | \$3,693 | \$352 |
| State cultivation tax revenue | \$105 | \$107 | \$2 |
| State excise tax revenue (15% of base) | \$381 | \$421 | \$40 |
| Sales tax, state revenue (7.25%) | \$184 | \$204 | \$20 |
| Sales tax, local revenue (1.05%) | \$27 | \$29 | \$2 |
| Local cannabis tax (8.2% of base) | \$208 | \$230 | \$22 |
| Local cultivation tax | \$91 | \$93 | \$2 |
| State tax revenue | \$671 | \$732 | \$61 |
| Local tax revenue | \$326 | \$352 | \$26 |
| Tax revenue | \$997 | \$1,084 | \$87 |
| Revenue without tax | \$2,345 | \$2,609 | \$265 |

Source: AIC simulations and calculations.

¹Averages, not totals.

Notes: Pounds are in dried flower equivalents. Rounding affects column sums.

Table 2c. Totals of both Medicinal and Adult-Use Cannabis: Impacts of Bureau regulations on prices, quantities, revenues, and taxes compared to the Taxation Baseline

| Variable | <i>Taxation Baseline</i> | <i>Taxation Plus Bureau Regulations</i> | <i>Difference</i> |
|--|--------------------------|---|--------------------|
| Retail full price to buyers (\$/lb.) | \$4,580 ¹ | \$4,983 ¹ | \$403 ¹ |
| Quantity (lbs.) | 1,305,583 | 1,339,348 | 33,765 |
| | | (\$ millions) | |
| Total Revenue | \$5,979 | \$6,674 | \$695 |
| State cultivation tax revenue | \$193 | \$198 | \$5 |
| State excise tax revenue (15% of base) | \$698 | \$779 | \$81 |
| Sales tax, state revenue | \$223 | \$247 | \$24 |
| Sales tax, local revenue | \$33 | \$36 | \$3 |
| Local cannabis | \$373 | \$416 | \$43 |
| Local cultivation tax | \$167 | \$171 | \$4 |
| State tax revenue | \$1,115 | \$1,225 | \$110 |
| Local tax revenue | \$572 | \$624 | \$52 |
| Tax revenue | \$1,687 | \$1,849 | \$162 |
| Revenue without tax | \$4,292 | \$4,825 | \$533 |

Source: AIC simulations and calculations.

¹ Averages, not totals.

Notes: Pounds are in dried flower equivalents. Rounding affects column sums.

6.3 Summary of economy-wide impacts of proposed regulations on the cannabis industry in California

The effects summarized in Tables 2a, 2b, and 2c were introduced into a modified IMPLAN model in order to estimate economy-wide impacts. These economy-wide impacts are summarized in this section. More discussion and comparisons, including detailed multiplier tables and economy-wide impacts, are provided in Appendix Chapter 9.

The IMPLAN database, which uses U.S. industry classifications, does not have cannabis industry categories. Therefore, to approximate the economy-wide impacts, AIC first specified industries that were as close a match as possible to the cannabis sectors required for the analysis. Next, the economic ratios in these matching industries were modified based on data for the corresponding cannabis sectors. For dispensaries, AIC modified some of the ratios in the retail drug store industry (IMPLAN industry 401) to better reflect shares of costs of goods sold. The allocation of industry revenue minus costs of goods sold to taxes and other costs was then modified using data that were available from the AIC review of cannabis dispensary accounting costs, a process that is detailed in Appendix Chapter 3.

For cannabis distribution businesses, the IMPLAN wholesale trade industry (IMPLAN industry 395) was the closest match. We adjusted the ratio of price to distributors minus costs of goods sold to better fit AIC data on cannabis costs. We also considered the high share of taxes in the cannabis sectors relative to most other marketing. Note that the dollar value of output for retail and wholesale industries in IMPLAN is based on the difference of price minus cost of goods sold times quantity in the sector. That is, these companies provide output in terms of wholesale or retail services added to the cost of goods that pass through the industry.

The closest IMPLAN match for laboratory testing of cannabis was medical and diagnostic laboratories. We adjusted the economic ratios for that sector to reflect estimates of cost categories of cannabis testing companies. In particular, cannabis testing costs are less labor intensive than medical and diagnostic laboratories, with more of the costs associated with capital and equipment.

As noted, AIC calculations in the IMPLAN analysis were based on the simulation model results for market prices and quantities (presented in Table 2a for medicinal cannabis, Table 2b for adult use cannabis, and Table 2c for combined legal cannabis). The model inputs included detailed data on costs of regulations, which were especially important for the testing sector. The IMPLAN results are presented as the change in the value of output, value added, and change in jobs compared to the baseline situation with adult-use cannabis legalization, but without the proposed Bureau regulations.

We first consider impacts based on the results of Table 2a for the medicinal segment. Based on the IMPLAN simulations, in the retail sector, the direct output in the sector (measured by revenue above costs of goods sold) rises compared to the no-regulations baseline by \$107.1 million, value added rises by \$83.3 million, labor income rises by \$45.6 million, and direct jobs rises by 1,125 jobs. After considering multiplier impacts, the California economy-wide value added rises by \$132.6 million, and 1,617 added jobs may be attributed to the increase in retail value of output. In the distribution sector (which includes transportation), margin rises by \$39 million and number of direct jobs rises by 187. The total number of jobs in California attributable to the distribution sector rises by 421.

Under the regulations, the expanded laboratory testing sector is subject to significant new economic activity. Revenue rises by \$34 million; direct value-added rises by \$11.7 million; and the number of direct jobs in the sector rises by 111. Economy-wide value added attributable to the testing expansion rises by \$109 million, and the number of jobs economy-wide rises by 360.

Overall, the economy adds 1,422 jobs in the medicinal cannabis sector. Overall, jobs in California attributable to medicinal cannabis rise by 2,399 due to the regulations.

Next we consider impacts associates with the adult-use cannabis sector as represented by the economic activity shown in Table 2b. The results are proportional to those for the medicinal sector and may be presented in the same order.

Based on the IMPLAN simulations for the adult-use segment, in the retail sector, the output in the sector (measured by revenue above costs of goods sold) rises compared to the no-

regulations baseline by \$106.6 million, value added rises by \$82.9 million, labor income rises by \$45.4 million, and direct jobs rises by 1,119 jobs. After considering multiplier impacts, the California economy-wide value added rises by \$131.9 million, and 1,609 added jobs may be attributed to the increase in retail value of output. In the distribution sector (which includes transportation), margin rises by \$37.6 million and number of direct jobs rises by 180. The total number of jobs in California attributable to the distribution sector rises by 406.

Under the regulations, the expanded laboratory testing sector is stimulated, generating significant new economic activity. Revenue rises by \$39.9 million; direct value added rises by \$13.8 million; and the number of jobs in the sector rises by 130. Economy-wide value added attributable to the testing expansion rises by \$128 million, and the number of jobs economy-wide rises by 423.

Overall, the economy adds 1,429 jobs in the adult-use cannabis sector. Overall, jobs in California attributable to the regulations of adult-use cannabis rises by 2,438 jobs due to the regulations.

It is informative to add the impacts for the medicinal and adult use segments to derive the impacts of proposed Bureau regulations on legal cannabis compared to the Taxation Baseline. These results are based on Table 2c and are simply the sum of the results for medicinal and adult use cannabis.

Based on the IMPLAN simulations for the full legal cannabis segment, the output in the retail sector (measured by revenue above costs of goods sold) rises compared to the Taxation Baseline, by \$213.7 million, value added rises by \$166.2 million, labor income rises by \$91 million, and direct jobs rises by 2,244 jobs. After considering multiplier impacts, the California economy-wide value added rises by \$264.5 million, and 3,227 added jobs may be attributed to the increase in retail value of output. In the distribution sector (which includes transportation), direct output (margin) rises by \$76.6 million and number of direct jobs rises by 368. The total number of jobs in California attributable to distribution sector rises by 827.

Under the regulations, the expanded laboratory testing sector is stimulated to significant new economic activity. Revenue rises by \$73.9 million; direct value added rises by \$25.5 million;

and the number of jobs in the sector rises by 240. Economy-wide value added attributable to the testing expansion rises by \$237.1 million, and the number of jobs economy-wide rises by 783.

Overall, the economy adds 2,852 direct jobs in the regulated cannabis sector. Overall, jobs in California attributable to the regulations of cannabis rises by 4,837 jobs.

These impacts are expected to be distributed geographically across California roughly in proportion with populations. Some evidence (discussed in Appendix Section 5) suggests that cannabis use is particularly prevalent among young adults. Thus, there may be some concentration of dispensaries and resulting multiplier effects in locations with more young people, including urban centers.

7. Assessment of whether the proposed regulations meet the “major regulation” standard in Government Code § 11342.548

After performing the analyses described in Section 6, we have determined that the total economic impact of the proposed regulations exceeds the one-year minimum threshold of \$50 million in impact (as measured by costs or benefits) required for the proposed regulations to meet the standard for a “major regulation” for the purposes of Government Code § 11342.548, and thus require a SRIA.

This SRIA calculates the impact of the Bureau’s proposed package of regulations by comparing the economic outcome in a hypothetical market situation without regulations in place against the economic outcome in the estimated situation with the proposed regulations also in place, holding other major economic factors constant. Using this definition of impact, we estimated that the effect on the total revenue, net of tax collections, on the legal cannabis segment is \$533 million per year. We calculated that effects of Bureau regulations on total consumer expenditure for legal cannabis, including taxes, would be \$695 million (because the tax revenue component is about \$162 million); see Table 2c for details.¹⁴³ We also note that these estimated impacts apply after some

¹⁴³ An alternative, narrower method of calculating the impact of the proposed regulations in isolation would be to compare the economic outcome in the situation with a set of minimum statutory requirements against

initial dislocations in the market are settled. We have not attempted to estimate impacts during the period of dislocation and flux after full implementation of taxation, adult-use legalization, other regulations and the proposed Bureau regulations.

Measured benefits of the proposed regulations to buyers are reflected in higher willingness to pay per pound of medicinal cannabis with the proposed regulations in place. Note that quantity rises slightly with substantially higher prices, thus consumer expenditures (retail revenue) rise significantly when industry per-unit costs rise and additional taxes are applied.

The direct economic impacts on the medicinal cannabis segment do not include multiplier impacts, as changes in the medicinal cannabis segment ripple through the rest of the economy. If these were included the impacts would be larger. By either measure, the estimates of costs or benefits are sufficient to meet the “major regulation” standard in Government Code § 11342.548.

8. Determination of the impact of the regulatory proposal on the state economy, businesses, and the public welfare (Government Code § 11346.3(c))

In Government Code § 11346.3(c), the markers to be used in assessing the economic impact of the proposed regulations in a SRIA are the following:

- (1) The creation or elimination of jobs in the state;
- (2) The creation of new businesses or the elimination of existing businesses in the state;
- (3) The competitive advantages or disadvantages for businesses currently doing business in the state;
- (4) The increase or decrease of investment in the state;
- (5) The incentives for innovation in products, materials, or processes; and
- (6) The benefits of the proposed regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, environment and quality of life, and any other benefits identified by the agency.

the economic outcome in the situation with the proposed regulations. That would require determining precisely the statutory minimum package of regulations and conducting a simulation of costs and benefits under a counter-factual baseline assuming those regulations applied.

Quantitative estimates in this section were based where possible on the IMPLAN projections of economy-wide impacts presented in Section 6.

Assessment 8.1. The creation or elimination of jobs in the state

As noted in Section 6, we estimate that the proposed regulations will increase jobs by an estimated 2,244 total jobs in the cannabis retail sector. The total effect on jobs in the cannabis retail sector, including ripple effects generated by both the adult-use and medicinal retail sectors, is an increase of 3,227 jobs.

The other major increase in jobs is in the cannabis laboratory testing sector. The IMPLAN results based on the AIC simulations project that the proposed regulations will create 240 new jobs directly and 783 new jobs when multiplier impacts are included. In the distribution sector of the legal cannabis industry, which includes transportation, the IMPLAN results based on the AIC simulations project that the proposed regulations will create 368 new jobs directly and 827 new jobs in total when multiplier impacts are included.

Overall, we estimated 2,852 direct jobs added within the legal cannabis industry due to the proposed regulations, and 4,837 jobs added in California after including multiplier effects. We expect these jobs to move, likely to urban areas, especially for laboratory testing, and in places where cannabis consumption is more prevalent.

Assessment 8.2. The creation of new businesses or the elimination of existing businesses in the state

AIC analysis of available data indicates that, on average, medicinal cannabis retailers sell about 600 pounds of cannabis each. If the total number of pounds sold increases by about 29,000 pounds and Table 2c, this would imply about 48 more retail operations state-wide due to the proposed regulations if average size of retail locations did not change. Of course, with significant new regulations many existing businesses may find their operations less suited to the regulatory environment and other businesses that may enter to replace some existing

businesses that exit. That means many new businesses enter and existing business leave even if the number of retail and distribution businesses overall change little.

Both creation and elimination of businesses is a natural occurrence for any significant change to the business conditions. Regulations related to license holder characteristics may cause some business to leave the segment because the current business owners find it difficult to meet requirements. Exits from the industry will generally be accompanied by other business entering or current businesses expanding.

The discussion in Section 6 indicate a large increase in the size of the cannabis laboratory testing sector. Table 2c reported that about 1.3 million pounds per year were projected to be sold in the hypothetical Taxation Baseline, and testing revenue for testing businesses were projected to be only \$2.6 million because testing is not required in that baseline. In the simulations with Bureau regulations added testing revenue is about \$100 million. Assuming that on average laboratories have revenues of about \$5 million, these figures imply about 20 laboratory testing businesses in the medicinal segment. We expect considerable variation with some very small operations and a few very large operations and more in the middle.

Information from industry sources indicates that in the middle of 2017, there were only a few medicinal cannabis testing laboratories operating in California that were equipped with the type of wet-lab facilities that would be necessary to conduct the required pesticide tests. Therefore, most testing businesses have been created as new businesses to help the industry comply with the proposed Bureau regulations. These businesses are expected to be located near distribution centers and spread across the state in major centers of retail sales.

MAUCRSA allows that a distribution license can be obtained by cultivators or retailers. We expect that with the Bureau regulations, as in 2017 in the medicinal cannabis segment, the distribution function be performed by a mix of cultivators, manufacturers, retailers, and micro-businesses, as well as specialized companies. Distribution cannot be done by testers. There is a large geographic spread of urban centers and rural areas with significant numbers of retailers around the state. Larger distribution businesses could realize cost advantages by locating near

clusters of retailers. The scope of this SRIA is the one-year period after regulations are fully implemented. As the industry matures in later years there may be fewer distributors as scale economies are achieved.

Overall, we estimate that about 5,000 new businesses enter and 6,000 existing businesses exit due to the Bureau regulations. The calculations treat each licensee as a distinct business. Many businesses eliminated are those that had been operating without regulatory compliance. These estimates are more than usually uncertain.

Assessment 8.3. The competitive advantages or disadvantages for businesses currently doing business in the state

AIC analysis indicates some advantages for businesses currently doing business in California. Recall that this SRIA shows estimates of the impacts of cannabis regulations imposed upon the cannabis industry relative to the baseline with taxation and adult-use legalization in effect. To be relevant, this sub-section therefore discusses competitive advantages and disadvantages relative to the counter-factual baseline, not relative to the situation in 2017 or before. Here, as elsewhere, we considered only the impact of the proposed regulations, with the baseline assumption that taxation, other regulation and adult-use legalization are in place.

AIC simulations did not include results that directly quantify the characteristics of businesses that may benefit or not from restrictions on vertical integration, and specifically, we have no quantitative information on how such restrictions may affect businesses currently in the industry relative to new entrants.

In general, the requirement that cannabis be transported to a distribution business before it is sent to a retailer changes current practices, but the ability for cultivators and retailers to also hold distribution licenses and for micro-business licenses to cover several activities reduces the impact of this requirement.

The MAUCRSA requires that current companies that own or operate both retail locations and testing labs either divest of one of the operations or set up new legal structures. This reduces the competitive advantages to a few businesses.

We expect that some businesses will adjust to the proposed regulations relatively easily, and that others will find adjustment too costly and will leave the industry. Given the nature of the adjustment costs, we expect businesses with strong management personnel and access to the capital and legal services necessary to meet the new regulatory standards, to adjust more readily, and thus to have a competitive advantage over new entrants. We expect that the existing businesses without these qualities, however, will be placed at a competitive disadvantage.

Sections 6 and 8 documented an increase in economic activity including revenue and jobs in cannabis laboratory testing. Subsection 8.2 projected several new laboratory testing businesses. AIC discussions with industry sources indicated that medicinal cannabis testing laboratories as they currently operate in California would not be fully compliant with the proposed regulations for medicinal or adult-use cannabis. The existing business needed to make adjustments to comply and new entrants designed their operations to be compliant.

Current medicinal cannabis laboratory testing businesses already operate in what is likely to be an expanding sector. The main disadvantage of pre-existing labs is that their services will require substantial upgrading to meet proposed regulations, which is costly and time-consuming. (See Appendix Chapter 6 for details, and see Appendix Chapter 10 for a discussion of laboratory testing concerns and dislocations experienced in other states.)

Most medicinal cannabis distribution and transportation operations were integrated with upstream or downstream businesses. Thus, there are few current distinct businesses in these sectors that are advantaged or disadvantaged.

Assessment 8.4. The increase or decrease of investment in the state

We estimated that the regulations will increase investment in California cannabis businesses relative to the baseline. As noted, overall legal cannabis revenue before tax will rise by about \$634 million from the Taxation Baseline, and this added revenue would be accompanied by investment. Some additional investment (for example in security equipment) in the distribution business sector would likely follow directly from proposed

regulations. Most retail locations would make additional investments to comply with the proposed regulations in that industry sector as well. Additional transport investment will likely be made mostly by business in the other business sectors that we anticipate would conduct much of the transporting.

As documented in Sections 6 and 8, many of the added costs of the proposed regulations are associated with laboratory testing. In order to generate about \$100 million in annual revenue, the laboratory testing sector will require a substantial increase in investment in equipment.

Assessment 8.5. The incentives for innovation in products, materials, or processes

MAUCRSA mandates that the proposed regulations include substantial new cannabis testing requirements. Information provided by government laboratory testing specialists and industry sources indicated that proposed regulations are likely to create incentives for innovations in testing procedures. For example, the proposed regulations create incentives for innovation to reduce costs for wet-lab testing machinery, perhaps including mobile testing laboratories. (More information on the testing requirements, incentives and potential innovations are provided in Appendix Chapter 6.) The proposed regulations create a few direct incentives for innovations in the other business sectors (distribution and retail). For example, packaging requirements will stimulate innovations in packages that are not accessible by children but attractive to customers.

Assessment 8.6. The benefits of the proposed regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, environment and quality of life, and any other benefits identified by the agency

8.6.1 Public safety benefits. The proposed regulations include a number of specific items related to public safety. These are discussed more fully in Section 12 and described in more detail in Appendix Chapters 6 and 12. In summary, video surveillance and archival requirements benefit public safety by improving the ability of licensing agencies to investigate bad actors, and by improving the ability of the Bureau and other agencies to document violations, collect penalties, and enforce sanctions on unlawful operations.

The proposed regulations may also benefit public safety insofar as they are able to help law enforcement apprehend criminals who are outside the jurisdiction of the Bureau. These security measures apply to transport, testing, distribution, and retail sectors of the cannabis industry.

The proposed track-and-trace system and other regulations that guard the integrity of the product as it makes its way through the supply chain benefit public safety by preventing the diversion of cannabis into the illegal market and becoming a source of income for criminal enterprises. We expect general safety benefits from careful regulation of an enterprise that has historically been linked with violent and harmful activity. In addition, we expect some deterrence of criminal activity due to the enhanced security measures from the proposed regulations. These benefits apply to security measures in the proposed regulations in all four industry sectors of the regulated cannabis segments, including transport and distribution, testing and dispensing. AIC has not quantified these benefits.

8.6.2 Public health benefits. As noted, the MAUCRSA and the proposed regulations include requirements for laboratory testing of medicinal cannabis. The proposed regulations may benefit the public by protecting consumers against the possibility of purchasing contaminated cannabis that many consumers wish to avoid. As noted above, our simulation model assumed an increased willingness to pay for cannabis that has been regulated and tested. The assumption was that this willingness to pay for testing offsets the cost of the proposed regulations such that quantity sold in the medicinal market is little affected by regulatory costs.

By comparison, relevant examples are abundant in the food sector. USDA's regulation of meat and poultry production and FDA's regulation of food manufacturers have been shown to increase willingness to pay in food markets. We anticipate that some buyers will pay the much higher prices in the taxed and regulated segments because of the safety and security of the product and the purchase environment.

In addition to testing, proposed regulations concerning the track-and-trace system may provide additional security against contamination and therefore public health benefits. Proposed Bureau regulations apply to both distribution businesses, and retailers. Appendix

Chapter 6 provides more information on proposed regulations in this area. Appendix Chapter 8 contains discussion and references on demand effects of food safety and traceability regulations. The safety assessment is limited by incomplete scientific evidence on safe levels of potential contaminants that is specific to cannabis.

A public health concern related to regulations relate to added costs and limited hours of availability that may reduce purchases of cannabis in the regulated market and increase use of illegal cannabis or substitute drugs that are much less safe. A common consideration of regulations that make buying the regulated product more costly or less available is the shift to unregulated products.

8.6.3 Worker safety. The proposed regulations include measures that reduce the risk of crime, thereby enhancing worker safety while improving public safety.

8.6.4 Environmental and other quality-of-life benefits. AIC analysis did not quantify specific environmental or other quality of life benefits of the proposed Bureau regulations. Recall that the proposed Bureau regulations have small impacts on the total quantity of cannabis produced or consumed in California. General quality-of-life benefits may occur in locations near to the regulated retailers because these licensed businesses will have more incentives to operate in ways conducive to good neighbor practices. With respect to environmental issues, some small additions to transport fuel use may follow from required transport to and from distribution businesses and to testing facilities.

There may also be environmental or quality-of-life benefits in neighborhoods where licensed retailers are located as they comply with security and related regulations and have an incentive to minimize environmental impacts that might be attributable to them. We expect that any such environmental impacts are likely to be relatively small. More significant environmental impacts may follow from regulations of the cultivation industry, which have been investigated in the context of those proposed regulations.

9. Benefits of the proposed regulations, expressed in monetary terms to the extent feasible and appropriate

Section 6 above described the overall economic impact of the regulations and highlighted perceived benefits of regulations to consumers in terms of higher willingness to pay per flower-equivalent pound of cannabis. As shown in Tables 2c in Section 6, there is an almost 3% increase in aggregate quantity of regulated cannabis sold with the proposed Bureau regulations.

We estimate that consumers are willing to buy more legal and regulated cannabis and pay approximately \$695 million more per year for about the same quantity of cannabis for benefits derived from the proposed Bureau regulations, compared to the Taxation Baseline. This monetary value indicates that consumers draw quantifiable benefits from the regulations.

These figures apply to the impacts within one year after the proposed Bureau regulations have been fully implemented and initial flux has settled down. For a longer time horizon—for example for the lifetime of the regulation—the impact would be far larger. Using a discount rate of 5% and assuming these benefits continue indefinitely, the present value of the sum of discounted benefits accrued into future years is given by: $\$695 \text{ million}/0.05 = \13.9 billion .

10. Types of costs considered for implementation of the proposed regulations

The costs to the industry necessary to comply with the proposed regulations comprise the most immediate, first-order costs. These costs are provided in detail below where we discuss regulatory alternatives in Section 12. Added costs include additional product testing, safety, and security measures that are discussed in Sections 6, 8, and 12. Fees to support the regulatory program compose a relatively small share of the whole.

AIC projected that the proposed Bureau regulations would have very small effects on the quantity of regulated cannabis consumed (Table 2a). Therefore, any social costs associated with the changes in the use of cannabis from proposed regulations would be small.

11. Effects on the General Fund, special state funds, and affected local government agencies attributable to the proposed regulations

As shown in Section 6, especially Table 2c, the proposed regulations increase sales revenue of retailers. Overall tax receipts are substantial and rise with the proposed Bureau regulations.

AIC simulations, reported in Table 2a, 2b, and 2c, estimate that the proposed Bureau regulations would increase total state tax receipts by about \$49 million for medicinal cannabis, \$61 million for adult-use cannabis, and \$110 million for all legal cannabis. Local government taxes on cannabis retail sales are also estimated to be substantial and, as shown in table 2c, rise with the regulations and retail revenues.

To estimate full economic and fiscal impacts of proposed regulations requires estimates of licenses fees associated with proposed Bureau regulations. We develop an estimated license costs of about \$60 million which is estimated to cover the expenses of the Bureau in operating the regulatory system for which it is responsible. With about 1.33 million pounds sold, the cost of license fees is about \$45 per pound.

12. Evaluation of two reasonable alternatives to the proposed regulations

This section introduces and provides analysis of two alternative regulations: a lower-cost package and a higher-security package of regulations. This section compares these alternatives relative to the proposed Bureau regulations. Summary description is provided in Table 3. Next, in Table 4, we assess testing costs in detail for each of the three packages of alternatives and provide the summary costs.

In Table 5, we add other regulatory costs in order to compare the total cost of each of the three packages of alternatives with the total cost of the proposed regulations. (Detailed calculations of the costs of the package of proposed regulations and the two alternative packages of regulations can be found in the Appendix Chapter 6.) Finally, simulations of economic impacts with the two alternative packages of regulations are compared to the proposed regulations.

12.1. Alternatives summarized

The two alternative sets of regulations can be compared to the proposed regulations in terms of three features of the packages, which are summarized in Table 3. With respect to item 4, hours of operation restrictions, we do not vary the higher-security alternative from the proposed regulations due to the fact that the proposed regulations are already as restrictive as any US state with an adult-use or cannabis industry.

Table 3. Major differences between the proposed regulatory package and two alternative regulatory packages with implications for direct costs of compliance

| <i>Impact Variable</i> | <i>Lower-cost alternative</i> | <i>Proposed regulations</i> | <i>Higher-security alternative</i> |
|--|--|--|--|
| 1. Maximum batch size for mandatory testing | • No maximum batch size | • 50 lb maximum batch size | • 10 lb maximum batch size |
| 2. Retailer-to-consumer delivery restrictions | • No restrictions on vehicle type • No lockboxes required • No restrictions on number of employees | • Cars only • Lockboxes required • No restrictions on number of employees | • Cars only • Lockboxes required • Deliveries must be made by 2 or more employees |
| 3 Security video archival requirements | • No requirements | • 1280x720, 15fps ¹ • 90 days archive | • 1280x1024, 20fps ¹ • 90 days archive |
| 4. Cannabis waste storage and disposal requirements | • No requirements | • Before disposal, all cannabis waste must be: 1. Rendered unrecognizable and unusable 2. Disposed of by a licensed waste hauler, with documentation | • Before disposal, all cannabis waste must be: 1. Disguised by blending with solid waste or soil 2. Weighed and labeled with bill of lading 3. Quarantined in a dedicated area on camera for 72 hrs |
| 5. Hours-of-operation retail restrictions | • No restrictions | • 6am-10pm | • 6am-10pm |

Source: AIC analysis of proposed regulations, MAUCRSA statutes, and AIC interviews with Bureau and CDPH.

¹ The terms “1280x720” and “1280x1024” indicate pixel resolution; the terms “15 fps” and “20 fps” indicate frames per second of recorded video; term “90 days archive” indicates length of time the business is required to store video.

As noted above, effects of the hours-of-operation restrictions reduce demand for legal cannabis and this affects the projected prices and quantities in the simulations (via a 2% increase in demand for legal medicinal and adult-use cannabis and a 1.5% increase in demand for illegal cannabis). Thus the hours restriction is incorporated into our total calculated impacts of the three alternatives as reported at the end of Section 12.

All the alternative regulatory packages include components of compliance costs for retailers and distributors that do not vary between packages, because for those components the proposed Bureau regulations not varying substantially from the minimum required under MAUCRSA.

The largest component of these additional compliance costs that are not varied in our packages of alternatives is the cost of child-resistant packaging, which is required by MAUCRSA. This cost is applied to distributors. We estimate the cost of compliance with this requirement at about \$43 per pound. As detailed in Appendix Section 6.4.3, we obtained this estimate by making assumptions about the distribution of package sizes at retail and comparing the cost of basic packaging (zip-lock plastic bags) without regulations vs. the cost of compliant packaging (plastic containers with ASTM-approved child-resistant push-and-turn lids) for each package size.

12.1.1 Testing. As required by MAUCRSA, with certain roles played by CDPH and DPR, the regulations include an array of contaminant, pesticide, and other tests that we estimate to cost approximately \$1,062 per test. Tests must be conducted by statute, so the cost per test does not vary between alternatives.

According to AIC’s analysis, proposed regulations impose contamination and pesticide tests that raise the cost of cannabis by approximately \$235 to \$414 per pound vs. the unregulated situation, including the value of lost inventory due to failure. For these calculations, we assume that 25% of product is pre-tested, 16% fails initial testing, 50% of initially failed product is remediated, and 50% of remediated product passes second-round testing.

Itemized testing compliance costs are shown in Table 4. Note that our testing cost estimates also include the costs of associated labeling, although those costs may be borne partly by testers and partly by distributors.

| Table 4. Itemized testing compliance costs | Lower-cost alternative | Proposed regulations | Higher-security alternative |
|---|-------------------------------|-----------------------------|------------------------------------|
| Max batch size to be tested | None | 50 | 10 |
| Lab costs | | | |
| Lab costs per lb passing and marketed | \$35.28 | \$57.31 | \$214.88 |
| Lost inventory costs | | | |
| Total lbs lost due to samples submitted for testing plus failed and destroyed product | 180,408 | 180,408 | 180,408 |
| Cost of lost inventory, per lb passing | \$199.84 | \$199.84 | \$199.84 |
| Remediation costs | | | |
| Cost of remediation per lb passing | \$1.82 | \$1.82 | \$1.82 |
| Total cost per lb passing testing | \$236.94 | \$258.97 | \$416.54 |
| Cost per lb without regulations | \$2.12 | \$2.12 | \$2.12 |
| Per lb difference vs. unregulated situation | \$234.82 | \$256.85 | \$414.42 |

Note: Assumes that the costs of logistics, materials, procedures within the lab, labor hand, and margin are internalized within test price.

Maximum testing batch size also affects the cost of testing per pound of cannabis sold, especially for cultivator businesses capable of producing large batches for testing. There is no requirement in MAUCRSA regarding batch size. Therefore, we set the lower-cost alternative with no maximum batch size. We estimate that the cost impact of the lower-cost alternative regulations (difference between the regulated and unregulated scenarios) would be approximately \$235 per pound.

The proposed testing regulations institute a more stringent set of pesticide tests than those in the lower-cost alternative and establish a 50-pound maximum batch size for testing. These requirements raise the cost of cannabis by \$257 per pound (against the unregulated situation), or about \$22 more per pound than the lower-cost alternative.

The higher-security alternative, which keeps the same set of tests in place but lowers the maximum batch size to 10 pounds, raises the estimated cost impact per pound of cannabis testing to about \$414. This is approximately \$157 per pound more than the proposed Bureau regulations. A smaller batch size may allow for more accurate testing. (More on testing and background on cost estimates is included in Appendix Chapter 6.)

12.1.2 Delivery methods. Retail cannabis deliveries are typically done by car. However, some urban dispensaries make deliveries on foot, bicycle, electronic bicycle (e-bike), or scooter at a significant cost savings. The proposed regulations prohibit on-foot, bicycle, e-bike, or scooter deliveries.

The lower-cost alternative places no regulatory restrictions on delivery methods. Delivery costs currently add approximately \$150 per pound to the average cost of cannabis. This estimate relies on the AIC price survey data that 40% of cannabis is transferred to consumers via delivery services. (See Appendix Chapter 4 for details on that estimation.) Allowing the lower-cost delivery methods lowers the average cost of cannabis in the state by approximately \$25 per pound compared with the proposed regulations.

Unenclosed vehicles do not allow as much security as enclosed vehicles. Attaching a lock-box to a person would be impossible, and attaching a lock-box to a bicycle, e-bike, or scooter would likely be impractical. With these delivery vehicles allowed, the security objectives of the proposed lock-box regulatory provisions would be ineffective at the delivery stage, increasing the potential for criminal activity in neighborhoods surrounding dispensaries.

A higher-security alternative is to require two employees to be in each delivery vehicle (one driver and one delivery representative), which would enable one employee to be with the cannabis inventory at all times. This would provide an additional level of security. The additional labor costs that would result from the higher-security alternative would increase the cost of cannabis by approximately \$138 per pound relative to the proposed regulations. (Appendix Chapter 6 provides details on the calculations of delivery costs with lower-cost and higher-security alternatives.)

12.1.3 Security video archival requirements. The MAUCRSA does not contain specific security video or archival requirements. The proposed regulation includes the requirement that licensees maintain security cameras with high enough quality for facial recognition (proposed to be 1280 x 720 pixels at 15 frames per second) covering many areas of the inside of and entrances to the building, and to maintain a 90-day video archive of footage from these cameras. The 90-day video archival requirement achieves the Bureau's enforcement objectives as well as law enforcement objectives not directly related to the Bureau's activities, but which have benefits to the public safety as discussed above.

We estimated that the average retail location will require either five or six cameras to achieve coverage. We estimated the cost per pound of retail cannabis (both medicinal and adult-use) to rise by approximately \$25 per pound (\$19.97 for the retail function, plus \$5.46 for the distribution and testing functions) compared with the lower-cost alternative, which requires no surveillance archive storage. We increase the proposed regulations' video surveillance requirement to 1280 x 1024 pixels at 20 frames per second in the higher-security alternative. (Appendix Chapter 6 provides our interpretation of the video requirements.)

12.2 Simulation results for alternatives

We introduced the two alternative regulation packages into the simulation model that we used to analyze impacts of the proposed regulations. Recall that the proposed regulations were assumed to shift out demand by 6% compared to the Taxation Baseline. Likewise, each of the alternative regulations were also assumed to raise demand relative to the baseline. The lower-cost alternative was assumed to shift out demand by 5% relative to the baseline. The higher-security alternative was assumed to shift out demand by 6% relative to the baseline.

We have outlined the explicit regulatory cost of each option. We also incorporate a 2% reduction in basic operating costs (as shown in Table 1) to recognize advantages of retailers operating in a regulated environment that has better enforcement, safety and security for retailers. This cost reduction partly offsets the higher cost impact of the proposed Bureau regulations compared with the Taxation Baseline.

Table 5. Estimated compliance costs per pound of alternative regulatory packages

| Cost/lb dried-flower equivalent | Lower-cost alternative | Proposed regulations | Higher-security alternative |
|---|---|----------------------|-----------------------------|
| License fees, distribution and retail | \$44 | \$44 | \$44 |
| Distribution and transport compliance, including child-proof packaging | \$46 | \$48 | \$52 |
| Retail-delivery-methods restrictions | None | \$10 | \$148 |
| Retail compliance, including waste storage and disposal, video surveillance archive, and other MAUCRSA-mandated regulations | \$25 | \$49 | \$86 |
| Testing compliance, including cost of license, pre-testing, testing and remediation, plus inventory lost due to testing samples and failed tests ¹ | \$235 | \$257 | \$414 |
| Hours of operation restrictions (closing at 10pm) | Not calculated on a per-pound basis. Included in simulation as: (1) a -2% shift in demand in medicinal cannabis segment; (2) a -2% shift in demand in adult-use cannabis segment; and (3) a +1.5% shift in demand in illegal cannabis segment. See Section 6.4.5 for details. | | |
| Total compliance costs per pound | \$350 | \$408 | \$744 |

Notes: Numbers in rows were rounded to the nearest \$1. See Appendix Chapter 6 for details. Cost components do not add up exactly to total costs, because of rounding.

¹See Table 4 for details.

The key results of simulations in the two alternative regulation packages are as follows. With the lower-cost alternative regulations, legal cannabis retail revenue is higher than the Taxation Baseline by \$665 million, and quantity sold is higher than the baseline by 43,755 pounds. With the higher-security alternative regulations, legal cannabis retail revenue is higher than the

baseline by \$641 million, but quantity is lower than the baseline by 57,549 pounds, or about 4.4%. In our estimation, the higher-security option would provide relatively little benefit as assessed by businesses and their customers, but imposes substantial extra costs. The implication is substantially smaller sales of medicinal or adult-use cannabis (and more sales in the illegal market) because the price is substantially higher.

These results can be compared with AIC simulation results for the proposed Bureau regulations as presented in Tables 2a–2c. Legal industry revenue is higher than the baseline by \$695 million, and quantity sold is higher than the Taxation Baseline by 33,765 pounds. Note that under both alternative sets of regulations, the increase in legal cannabis retail revenue relative to the baseline is less than the increase in revenue under the proposed regulations. Detailed calculations underlying these conclusions are reported in Appendix Chapter 8 and 9.

13. Final remarks

This SRIA summarized the AIC economic analysis of proposed regulation of the cannabis industry in California. Specifically, we considered regulations governing retailing, testing, and distribution. The proposed Bureau regulations were projected to affect economic costs or benefits to industry participants by more than \$50 million within the first year after taking full effect and the market had settled, compared with the baseline relevant to implementation of Bureau regulations. As discussed in some detail, the relevant baseline assumes adult-use legalization, taxation and other regulations, but not the proposed Bureau regulations.

Among the most costly aspects of the proposed regulations is laboratory testing, especially the loss of valuable product that fails to pass the stringent required tests. However, the assessment presented in this SRIA was that such testing also is likely to raise willingness to pay for medicinal cannabis, and that benefits thus offset costs. Other aspects of the proposed Bureau regulations that add to costs and thereby reduce quantity of cannabis sold in the regulated segments include license fees, track and trace, and child-resistant packaging. In addition, the prohibition on retail operations after 10pm is also estimated to have a significant negative impact on demand for legal cannabis relative to the Taxation Baseline without Bureau regulations.

The proposed Bureau regulations increase economic activity and jobs in the legal and regulated cannabis segments. The analysis used a standard approach to assess economy-wide “multiplier” effects, and found that the added economic activity in the cannabis segment raises economic activity broadly in the state.

Economic Costs and Benefits of Proposed Regulations for the Implementation of the Medicinal and Adult Use Cannabis Regulation and Safety Act (MAUCRSA)

Appendix to a Standardized Regulatory Impact Analysis for the Bureau of Cannabis Control in the California Department of Consumer Affairs

5 April 2018

Prepared by the University of California Agricultural Issues Center

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***Economic Costs and Benefits of Proposed Regulations for the Implementation
of the Medicinal and Adult Use Cannabis Regulation and Safety Act (MAUCRSA)***

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Introduction

This report provides background research and documentation for a Standardized Regulatory Impact Analysis (SRIA) of the Bureau of Cannabis Control's proposed regulations implementing the statutory requirements of California's Medicinal and Adult Use Cannabis Regulation and Safety Act of 2017 (MAUCRSA), which amended and replaced the Medical Cannabis Regulation and Safety Act of 2015 (MCRSA) and the Adult Use of Marijuana Act of 2016 (AUMA). This report functions as an appendix to the executive summary of methodology and results presented in the main SRIA.

We begin by laying out the legal background related to the regulations under consideration and the requirements for a SRIA. This provides the specific context for the economic analysis to follow. Chapter 1 presents the context and authority, and Chapter 2 presents the statutory and regulatory history and situation.

Because cannabis is illegal under federal law, official data are scarce and incomplete. In Chapters 3 through 5, we provide data that offer a snapshot of the California cannabis industry as it stood in late 2017, including both the legal (medicinal) and illegal market segments. We provide background on costs (Chapter 3), prices (Chapter 4), quantities (Chapter 5), and demand characteristics (Chapter 5) from a variety of sources, including a survey of medicinal retailers operating in 2017. In Chapter 6, we provide data and analysis on the compliance costs of the proposed regulations and of two alternative packages of regulations: a lower-cost alternative and a higher-security alternative.

Chapter 7 is more technical and mathematical than the previous chapters. It lays out in detail the economics underlying the model we developed to simulate the impact of proposed regulations on the cannabis industry in California. Chapter 8 provides the detailed background assumptions for our simulation model and reports our simulation model results for the proposed regulations and the two alternatives. Those results are presented in Table 8.2.

Chapter 9 uses the results of Table 8.2 to derive economy-wide impacts of the proposed cannabis regulations. The impacts on value added, labor income, and jobs are measured as differences between the pre-regulation situation and the three post-regulation scenarios (the proposed regulations and two alternatives).

Preliminary note on methodology

In order to calculate the impacts we estimate in chapters 8 and 9, we first began by observing and empirically estimating the economic situation for the cannabis industry in late 2017, in which medicinal and adult-use cannabis possession and use were legal, medicinal cannabis sale was legal but unregulated, and adult-use cannabis sale was illegal and unregulated. We arrived at these estimates using the costs, prices, quantities, and demand characteristics based on late-2017 empirical data, which are discussed in detail in Chapters 3, 4, and 5. We refer to this market landscape as the “Late 2017 Situation.”

Next, we calculated the baseline impact of a number of effects that we expected would occur in 2018, but which lie outside the scope of the Bureau’s regulations. The first such effect was the legalization of adult-use sale and the opening of the adult-use cannabis retail market to all California and out-of-state adults 21 and over, thus creating a third legal commercial market segment (adult-use cannabis) that as of 2018 competes with the two previously existing market segments (medicinal cannabis and illegal cannabis).

The second effect outside the scope of the Bureau’s regulations was the introduction of a number of state cannabis-specific taxes established under MAUCRSA, as well as various local cannabis-specific taxes and regulations established by a wide variety of county-level and municipal-level legislation that take effect in 2018. The third effect outside the Bureau’s regulatory scope is the sets of regulations that were propagated by the California Department of Food & Agriculture (CDFA) and California Department of Public Health (CDPH) to regulate cannabis cultivation and manufacturing businesses beginning in 2018.

Under MAUCRSA, a cannabis business may apply for a single microbusiness license that allows the business to operate under a single license in multiple segments: cultivation,

level 1 manufacturing, distribution, and retail. If a microbusiness has both medicinal and adult-use cannabis, then two microbusiness licenses would be needed. The restrictions on a microbusiness are that it may use such a license to conduct cultivation on an area of less than 10,000 square feet; and that it may only conduct level 1 manufacturing, which refers to making cannabis products using nonvolatile solvents, or no solvents. Note there are no size restrictions on distribution or retailing in the microbusiness license provisions.

The Bureau has responsibility to issue licenses to cannabis microbusinesses. However, the cultivation and manufacturing activities of microbusinesses must meet the same provisions in the associated regulations covering other license types (as issued by other agencies) for those activities. The state and local cultivation and manufacturing taxes and regulatory costs have already been included in the economic analyses of cultivation and manufacturing done for the SRIA of the California Department of Food and Agriculture or the California Department of Public Health, along with their analyses of cultivation or manufacturing activities under other licenses.

The distribution and retail activities of microbusiness license holders are analyzed in this SRIA. To avoid double counting, we do not include impacts of the cultivation regulations or the manufacturing regulations that cover microbusinesses. That is, this SRIA treats the cultivation and manufacturing conducted under microbusiness licenses in the same way that it treats those activities when conducted under other license types.

In sum, we constructed a hypothetical situation in which adult-use cannabis sale, cannabis-specific taxation, and the CDFA and CDPH regulations were in place, but the Bureau's regulations were not yet in place. As the actual impacts of the Bureau's regulations were expected to occur simultaneously to these other impacts in 2018, this hypothetical situation will never come to pass, but it was necessary to construct in order to isolate and observe separately the Bureau's proposed regulations as accurately as possible in light of the many confounding factors we observe in this market. We called this

hypothetical situation the “Baseline with State and Local Cannabis Taxation, Adult-Use Sale, and CDFA and CDPH Regulations, Without Bureau Regulations.”

In the interest of brevity, given that the majority of cost differences between the Late 2017 Situation and this hypothetical situation are the results of state and local taxation, we abbreviated the hypothetical situation as the “Taxation Baseline,” and we estimated the impacts of the shift between the Late 2017 Situation and the Taxation Baseline on all segments of the California cannabis industry. As the Bureau does not have discretion in its regulations to affect any of the changes that will occur as a result of adult-use sale, or state or local taxation, this step provides the baseline against which the proposed regulations may be measured.

Finally, our third step, and central focus of this SRIA, was to calculate and simulate the impact of the proposed regulations on the medicinal and adult-use cannabis segments separately from the effects of taxation. We called this final market scenario “Proposed Regulations.”

To evaluate the effects of the Bureau’s proposed regulations, we considered the post-regulation situation one year after the proposed regulations considered in this SRIA (as well as taxation, adult-use sale, and other agencies’ regulations) take effect.

Our analysis used an equilibrium displacement model to arrive at estimates of what market prices and quantities would be after the proposed Bureau regulations and regulatory alternatives have affected the supply and demand conditions. The estimated impacts were generated by a simulation of conditions projected to prevail with regulations fully implemented and after businesses and consumers have adjusted to the new conditions. We do not attempt to evaluate the situation during the interim transition phase.

The direct supply and demand shifts that will result from the proposed regulations are based on data and calculations presented in Chapters 5 and 6. Chapter 7 derives our simulation model and explains the assumptions and parameters of our model in detail.

Chapters 8 and 9 report results of simulations of the market situation one year after regulations are fully implemented and the market has settled. The focus of the simulations is on the impact of the Bureau’s proposed regulations.

The final sections of the report, Chapters 10 to 13, provide useful background information that helps document our modeling and parameter choices and data used in the analysis.

In sum, this report serves as a background appendix to the main SRIA. It contains material useful in understanding and interpreting the regulatory impact analysis provided in the SRIA.

1. Context and authority

1.1 Background legal setting

For the two decades since the 1996 passage of the Compassionate Use Act (Proposition 215), the ballot initiative that made California the first state in the United States to decriminalize the use of medicinal cannabis, California’s medicinal cannabis industry has been operating under an inconsistently enforced patchwork of local ordinances, with little state-level oversight.

The Medical Cannabis Regulation and Safety Act (MCRSA), passed in 2015 as Assembly Bill 266, Assembly Bill 243, and Senate Bill 643, establishes a Bureau of Cannabis Regulation (Bureau) within the California Department of Consumer Affairs (DCA). The Bureau is tasked with setting up and administering a licensing and enforcement system governing the distribution, transportation, testing, and retail sale of medicinal cannabis in California.

The Control, Tax and Regulate Adult Use of Marijuana Act (AUMA), passed on November 8, 2016, via the ballot initiative known as Proposition 64, eliminates criminal penalties for possession and use of cannabis by adults over 21, re-names the Bureau the Bureau of Marijuana Control (BMC), assigns the Bureau responsibility for also regulating California’s

adult-use cannabis industry, establishes a new legal regulatory structure for adult-use cannabis, and establishes new taxes on both medicinal and adult-use cannabis.

The implementing language of the California State Budget Bill of 2017, signed by the Governor and chaptered as Senate Bill 94 (SB 94) on June 15, 2017, modifies certain provisions of and resolves conflicts between MCRSA and AUMA in order to “provide for a single regulatory structure for both medicinal and adult-use cannabis.” SB 94 is known as Medicinal and Adult-Use Cannabis Regulation and Safety Act (hereafter “MAUCRSA”).

This Specialized Regulatory Impact Analysis (SRIA) was commissioned by the Bureau for the purpose of calculating the costs and benefits of MAUCRSA, incorporating the implications of SB 94, and considering the new single regulatory structure in calculating the expected economic impact of the Bureau’s proposed regulations governing the legalization, regulation, and taxation of medicinal and adult-use cannabis. This SRIA was prepared by the University of California Agricultural Issues Center (AIC).

1.2 Nature and scope of regulatory impacts considered

We analyzed the cannabis industry in California in the context of both the adult-use and medicinal cannabis segments, which must also take into account the illegal cannabis segment. The medicinal segment is so closely related to the adult-use segment that impacts of regulations must be considered in the broader context of all cannabis sold in California. After estimating economic effects within the medicinal cannabis segment, we used a standard economy-wide model to project ripple effects on the California economy more broadly.

At the heart of our analysis is an evaluation of the costs and benefits of three possible sets of cannabis regulations, which we call “regulatory packages”: (A) the regulations currently proposed by the Bureau; (B) an alternative package of regulations that would be less costly than the proposed regulations while still fulfilling the minimum statutory requirements of MAUCRSA; (C) an alternative package of regulations that would impose

higher security standards than the proposed regulations, at a higher cost. These costs and benefits are considered with respect to (1) California businesses, (2) California consumers, and (3) the California state government.

2. Statutory and regulatory background

2.1 Compassionate Use Act (1996)

The ballot initiative known as Proposition 215 made California the first state to decriminalize medicinal cannabis. In the 20 years since then, the state has played a limited role in regulating medicinal cannabis. Legal guidelines coming from the state that has exerted influence on the behavior of medicinal cannabis businesses and patients have been largely limited to Senate Bill 420 (see Section 2.2) and the non-binding Brown Guidelines (see Section 2.3).

2.2 Senate Bill 420 (2003)

In 2003, the California Legislature passed Senate Bill 420, which added (section 11362.7 *et seq.* to the California Health and Safety Code relating to controlled substances. SB 420 established a basic framework for the legal operation of medicinal cannabis entities.

2.3 Brown Guidelines (2008)

In 2008, the laws regarding medicinal cannabis were clarified for operators of medicinal cannabis entities in an opinion issued by then-Attorney General Jerry Brown, an opinion many of the industry operators we spoke with cite as their canonical reference document on how to comply with California state law in the pre-regulation environment. Municipal and county ordinances generally concur with the Brown Guidelines but otherwise vary widely in their local regulation and licensing approach, ranging from a total prohibition on

the medicinal cannabis industry in some areas to robust ordinances in others (Mendocino, San Francisco, and Oakland, for instance) to a total lack of regulation in some rural areas of California.

2.4 Compliance with SB 420 and Brown Guidelines to date

Operators' degrees of compliance to SB 420 and the Brown Guidelines have been widely divergent. In the absence of an agency to supervise the state's medicinal cannabis businesses, these documents have generally served more as loose behavioral guidelines than as functioning rules.

Nonetheless, operators seem to have been consistent in their observance of the Brown Guidelines standards. Most retail storefronts operating as of late 2017 require patients to submit the original hard copy of their physician's recommendation (which is checked against a database maintained by the prescribing physician's office), an original document verifying California residency, and a completed medicinal intake form before they can purchase medicinal cannabis or even enter the area of the store in which products are displayed.

In many cases, retail operators have cited local (rather than state) enforcement as their primary incentive to follow the Brown Guidelines. In other segments within the medicinal cannabis industry, on the other hand, the Brown Guidelines appear to have been less consistently observed amongst delivery services without fixed retail locations, and private, low-profile medicinal collectives who do not advertise their services to their public. Such businesses may not observe the medicinal recommendation or California state residency requirements, for instance, in spite of their participation in the legal medicinal cannabis segment.

2.5 Medicinal and Adult Use Cannabis Regulation and Safety Act (2015–2017)

The Medicinal and Adult Use Cannabis Regulation and Safety Act (MAUCRSA), codified in its current form as SB 94, refines and resolves conflicts in the legislation previously known as the Medical Cannabis Regulation and Safety Act of 2015 (MCRSA) and the Adult Use of Marijuana Act of 2016 (AUMA), which legalized adult-use cannabis in California in November 2016 as required by the passage of Proposition 64.

MAUCRSA amends various sections of California Business and Professions Code, Health and Safety Code, Food and Agricultural Code, Revenue and Taxation Code, and Water Code, and introduces a new state-wide structure for the governance of the California cannabis industry as well as a system by which the state may collect licensing and enforcement fees and penalties from cannabis businesses.¹⁴⁴

The Bureau shares responsibility for promulgating and enforcing regulations implementing MAUCRSA with the California Department of Public Health (CDPH), the California Department of Food and Agriculture (CDFA), and a number of other state agencies. The responsibilities assigned to the Bureau include the issuance of licenses to and the collection of license and penalty fees from medicinal cannabis distributors, storefront and delivery retailers, testing laboratories, and transport-only distributors. The

¹⁴⁴ MAUCRSA amends Sections 26000, 26001, 26011, 26012, 26013, 26014, 26030, 26031, 26038, 26040, 26043, 26044, 26050, 26052, 26053, 26054, 26054.2, 26055, 26057, 26058, 26060, 26061, 26063, 26065, 26066, 26070, 26070.5, 26080, 26090, 26101, 26104, 26106, 26120, 26130, 26140, 26150, 26151, 26152, 26153, 26154, 26155, 26160, 26161, 26180, 26181, 26190, 26191, 26200, 26202, 26210, and 26211 of; amends the heading of Chapter 10 (commencing with Section 26100) and the heading of Chapter 13 (commencing with Section 26130) of Division 10 of; amends the heading of Division 10 (commencing with Section 26000) of; adds Sections 26010.5, 26013.5, 26046, 26047, 26050.1, 26060.1, 26121, 26131, 26132, 26133, 26134, and 26135 to; adds Chapter 6.5 (commencing with Section 26067) to Division 10 of; adds and repeals Section 26050.1 of, repeals Sections 26032, 26033, 26054.1, 26056, 26056.5, 26064, 26067, 26100, 26102, and 26103 of; repeals Chapter 3.5 (commencing with Section 19300) of Division 8 of; repeals Chapter 17 (commencing with Section 26170) of Division 10 of, and repeals and adds Sections 26010, 26034, 26045, 26051, 26062, and 26110 of, the Business and Professions Code; amends Sections 37104 and 81010 of the Food and Agricultural Code; amends Sections 11006.5, 11014.5, 11018, 11018.1, 11018.2, 11018.5, 11032, 11054, 11357, 11358, 11359, 11360, 11361, 11361.1, 11361.5, 11362.1, 11362.2, 11362.3, 11362.4, 11362.45, 11362.7, 11362.71, 11362.712, 11362.713, 11362.715, 11362.745, 11362.765, 11362.768, 11362.77, 11362.775, 11362.78, 11362.785, 11362.79, 11362.795, 11362.8, 11362.81, 11362.83, 11362.85, 11362.9, 11364.5, 11470, 11478, 11479, 11479.2, 11480, 11485, 11532, and 11553 of; amends the heading of Article 2 (commencing with Section 11357) of Chapter 6 of Division 10 of; and repeals Sections 11362.72, 11362.735, 11362.74, 11362.755, 11362.76, and 11362.777 of the Health and Safety Code; amends Sections 34010, 34011, 34012, 34013, 34014, 34015, 34016, 34018, 34019, and 34021.5 of; and amends the heading of Part 14.5 (commencing with Section 34010) of Division 2 of the Revenue and Taxation Code; and amends Sections 1831, 1847, and 13276 of the Water Code relating to cannabis.

Bureau was initially funded with a \$10,000,000 startup loan from the state General Fund, which is to be paid back with proceeds from licensing fees collected by the Bureau.

In this SRIA, we rely on the working assumption that medicinal cannabis and adult-use cannabis are to a large extent substitutable.¹⁴⁵ This implies that businesses in these two parallel systems will thus compete for customer demand, and that the systems themselves will compete with each other for new entrants in the sense that entrants will weigh the pros and cons of each. That is, in the short run, prices in the adult-use cannabis segment will be likely to affect quantities transacted in the medicinal cannabis segment. If the price of adult-use cannabis is significantly lower than the price of medicinal cannabis, then consumers will be likely to demand less medicinal cannabis and more adult-use cannabis; if the price of medicinal cannabis is significantly lower, then consumers will be likely to do the opposite.

2.6 Temporary Emergency Regulations

On January 1, 2018, as required by MAUCRSA, taxation and adult-use sale legalization of cannabis began in California. Temporary emergency regulations were implemented. These emergency regulations included some but not all of the proposed regulations evaluated in this SRIA. Temporary licenses were granted to businesses based on provisional applications. Businesses applying for temporary licenses were not required to pay full license fees. Some testing requirements were waived for inventory that had entered the commercial stream in 2017. We did not include any 2018 data to construct our initial situation estimates. We updated our estimates of the pre-taxation scenario based on late (November/December 2017) data, including our own November 2017 AIC Retail Cannabis Price Survey and December 2017 wholesale spot price data from Cannabis Benchmarks, which were collected before the implementation of temporary emergency regulations.

¹⁴⁵ In much of the literature, medicinal cannabis is referred to as “medical marijuana” and adult-use cannabis is referred to as “recreational marijuana.”

3. Background on operating costs for cannabis retailers

Between fall 2016 and mid-2017, through a series of confidential informal interviews and information requests guaranteeing respondents' anonymity, AIC assembled a set of hypothetical income statements from California medicinal cannabis retailers operating as of late 2017 in four broad size categories constructed for the purpose of roughly representing the distribution of retailers of various sizes across the state.

We developed idealized estimates of itemized retailing cost and revenue line-item averages for four different idealized representative retail establishment sizes. Retailers were sorted into these four idealized categories based on their annual revenues. The model retailer in the first category, which we call "micro," received approximately \$1,000,000 in annual revenue from selling 290 flower-equivalent pounds (defined in Section 5.3.1), at an assumed retail price of approximately \$3,400 per pound (derived from calculations on data from the AIC cannabis retailer survey in mid-2017; note that this differs slightly from the late 2017 estimate of \$3,600 per pound).

The second idealized retailer category, "small," averages \$2.4 million in annual revenue and 695 flower-equivalent pounds sold per location. The third idealized category, "medium," averages \$6 million in annual revenue and 1,738 flower-equivalent pounds sold per location. The fourth idealized category, "large," averages \$24 million in annual revenue and 6,950 flower-equivalent pounds sold per location.

Separating retailers into four categories was necessary to account for the considerable economies of scale in larger operations and arrive at a reasonable approximation of the business landscape in order to calculate the effects of regulations on costs per flower-equivalent pound of selling cannabis at retail. In the interest of simplicity, we did not account for any possible retail price differences between retailers of different sizes.

An AIC review of these costs suggested that as of late 2017, background operating costs for cannabis retail establishments had not substantially changed since fall 2016. Given the

roughness of the estimates, we thus proceeded by assuming these background operating costs remained in place as of late 2017. We did, however, incorporate the latest available (November/December 2017) industry estimates of wholesale cannabis prices into this SRIA.

3.1 Raw material costs

The single largest component of retailing costs is the cost of raw materials (in this case, dried cannabis flower). Raw material costs are not the subject of our analysis but are important for understanding the industry cost structure. As of November/December 2017, US wholesale prices for dried cannabis flower were approximately 38% of retail price, based on the Cannabis Benchmarks data (described and cited in Tables 3.1 and 3.2 and Figure 3.1) and the latest AIC Retail Cannabis Price Survey data reported and discussed in Chapter 4. As of mid-December, 2017, the four-week trailing average US spot wholesale price from Cannabis Benchmarks was approximately \$1,350 per pound of dried flower. This represented an increase of 2.7% over the previous 12 months (in August 2016, it had stood at \$1,314).¹⁴⁶

The average wholesale price of cannabis is derived as a weighted average of three dried-flower cultivation methods, each of which commands different wholesale prices in the marketplace. The three cultivation methods are outdoor (natural light), indoor (artificial light), and greenhouse (mixed light) growing. Changes in wholesale prices are determined in large part by changes in the relative shares of outdoor-grown, greenhouse-grown, and indoor-grown cannabis transacted in the wholesale market.

Month-to-month changes in the respective shares of these three cultivation types, in turn, are driven in part by natural seasonal fluctuations that have been consistently observed in past years: specifically, when the once-per-year outdoor harvest occurs in the fall, a large

¹⁴⁶ Data from Cannabis Benchmarks Weekly Premium Reports (2016, 2017).

amount of outdoor-grown cannabis is introduced to the market. Outdoor-grown cannabis thus makes up a considerably larger share of all cannabis sold in the fall and winter.

To observe seasonal wholesale price trends in the California cannabis market, we analyzed California wholesale cannabis price data for the one-year period between August 2016 and August 2017. Outdoor-grown cannabis is priced consistently lower at wholesale than indoor or greenhouse prices (which ranged from \$1,000 to \$1,200 per pound between August 2016 and August 2017, vs. \$1,600 to \$1,900 for the weighted average of indoor and greenhouse-grown cannabis). This generally results in relatively lower overall wholesale prices for cannabis during the fall and winter months, when more inexpensive outdoor-grown cannabis makes up a larger proportion of all cannabis.

In fall-winter 2016, weighted average wholesale prices generally ranged from \$1,300 to \$1,500, whereas prices ranged from \$1,500 to \$1,600 in summer 2016 and summer 2017 as the supply of outdoor-grown cannabis (which can only be harvested once per year) dissipated over time and was replaced in the wholesale market by more expensive indoor- and greenhouse-grown cannabis (which can be harvested several times per year).

In Table 3.1, we report the trends in outdoor, greenhouse, and indoor wholesale cannabis prices for the year between August 2016 and August 2017. These data illustrate the increase in prevalence of outdoor product in January 2017 following the outdoor harvest, and the subsequent fall in prevalence of outdoor product by August 2017.

With respect to overall weighted average wholesale prices, the trend downward in the fall/winter and upward in the spring/summer are driven largely by the mix of outdoor vs. indoor product on the wholesale market.

Year-on-year, we note an overall trend of falling prices for wholesale outdoor cannabis (down 9% year-on-year) and rising prices for wholesale greenhouse (up 1% year-on-year) and indoor (up 2% year-on-year). The rising weighted average price for wholesale

cannabis (up 3% year-on-year) is generated by a shift toward more expensive indoor-grown product.

Table 3.1. California wholesale cannabis prices, August 2016–August 2017

| Cultivation method | August 2016 ¹ | January 2017 ² | August 2017 ³ |
|-------------------------|--------------------------|---------------------------|---------------------------------------|
| Outdoor | \$1,187 | \$1,107 | \$1,078 (↓ 9% YOY ⁴) |
| Outdoor % by volume | 23% | 49% | 23% ⇔ |
| Greenhouse | \$1,525 | \$1,567 | \$1,536 (↑ 1% YOY ⁴) |
| Greenhouse % by volume | 41% | 23% | 28% ↓ |
| Indoor | \$1,752 | \$1,906 | \$1,793 (↑ 2% YOY ⁴) |
| Indoor % by volume | 37% | 28% | 51% ↑ |
| Weighted average | \$1,533 | \$1,442 | \$1,565 (↑ 3% YOY⁴) |

Note: Percentages may not add exactly to 100% due to rounding.

¹ Avg of four weeks' avg spot prices beginning 29 July 2016. Source: Cannabis Benchmarks Premium Reports.

² Avg of four weeks' avg spot prices beginning 30 December 2016. Source: Cannabis Benchmarks Premium Reports.

³ Avg of four weeks' avg spot prices beginning 28 July 2017. Source: Cannabis Benchmarks Premium Reports.

⁴ YOY = year-on-year change.

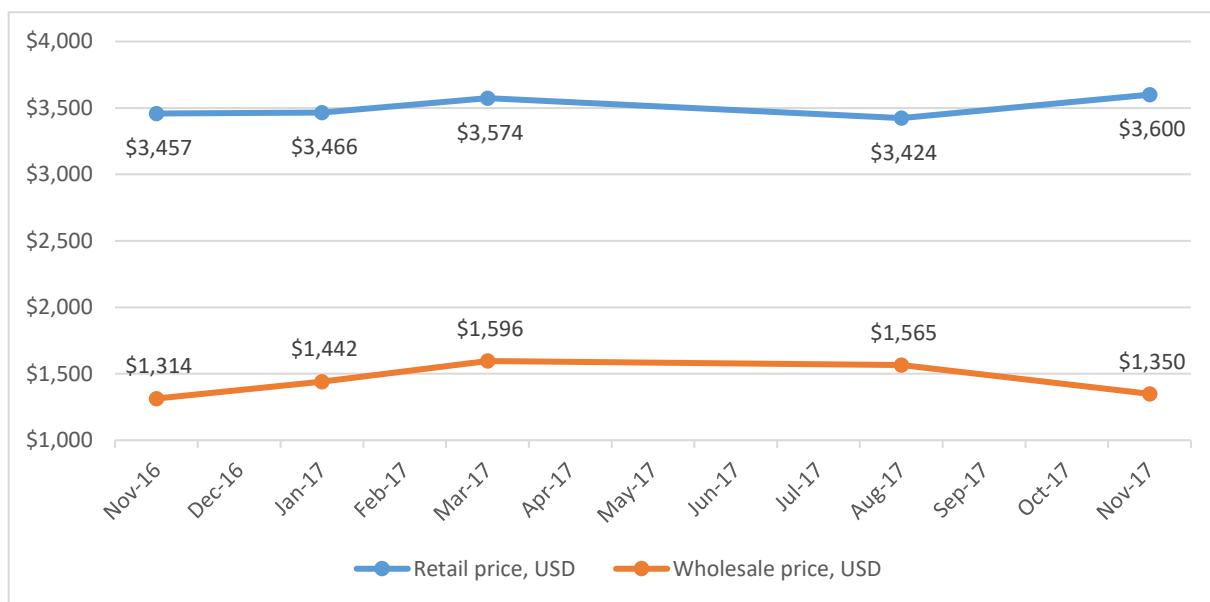
Although data-collection methodology employed by Cannabis Benchmarks may favor less secretive, slightly-more-expensive-than-average suppliers of raw material, these are also the types of suppliers most likely to participate in the 2018 regulated market, so we use Cannabis Benchmarks data to set our working estimates. For the purposes of this SRIA, we constructed a weighted average of late 2017 (mid-December trailing average, thus November/December) Cannabis Benchmarks wholesale spot prices to arrive at an estimate of \$1,350 per pound before applying taxation and regulations.

**Table 3.2. Average California cannabis markup, 1 lb dried flower
Year-on-year comparison, Nov 2016 vs. Nov 2017**

| | Nov-16 | Nov-17 |
|-----------------|---------|---------|
| Retail price | \$3,457 | \$3,600 |
| Wholesale price | \$1,314 | \$1,350 |
| Markup | 163% | 167% |

Source: Cannabis Benchmarks; AIC Retail Cannabis Price Survey.

**Figure 3.1. California retail and wholesale cannabis prices, 1 lb dried flower,
Seasonal fluctuations over one-year period, Nov 2016 to Nov 2017**



Source: Cannabis Benchmarks Premium Reports; AIC Retail Cannabis Price Survey.

3.2 Retail margins and risk-premium (Federally illegal trade) effects

The commercial sale and possession of cannabis remains largely illegal under Federal law. Therefore, all operators of cannabis businesses in California risk violating Federal law.

An economic situation in which industry participants are operating legally or partially legally with respect to state law and still fully illegal on a federal level presents many cost-related concerns. Atypical business risks (e.g., arrest, seizure of property) as well as atypical business challenges (e.g., the vagaries of local municipal law, denial of access to the banking system) face cannabis cultivators, intermediaries, and retailers compared with the farmers, intermediaries, and retailers of other agricultural products. Such risks drive up business costs across the board, especially labor costs. For example, workers willing to risk arrest expect to be rewarded with premium wages. According to Krissman

(2016), cannabis trimmers in California command a 200% wage premium over the market for agricultural labor.

Such extra business costs have a direct effect on consumer prices. The extra price paid by consumers for the products of industries that face uncertain and sizable losses is sometimes known in economics as the “risk premium.” Sifaneck et al. (2007), for example, observed a street price of up to \$80 for one-eighth ounce of generic cannabis from a New York City delivery service in the mid-2000s in New York, where criminal restrictions for cannabis sale and possession were tightly enforced. Before adjusting for inflation, this is approximately double our estimate of the average price for generic delivery-service cannabis in California.

3.2.1 Rohrenbacher-Blumenauer Amendment and conflicts with Federal law. The U.S. Senate has extended the effective period of the Commerce, Justice, Science, and Related Agencies Appropriations Act (S. 1662), also known as the Rohrenbacher-Blumenauer Amendment (previously, the Rohrenbacher-Farr Amendment, introduced 2003, passed in 2014). The Amendment prevents the United States Department of Justice from spending funds to interfere with state medicinal cannabis. As in previous versions of Rohrenbacher-Farr, the current language of Rohrenbacher-Blumenauer is specific to “medical marijuana” and does not mention adult-use cannabis. The Amendment reads, in full:

None of the funds made available in this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, Guam, or Puerto Rico, to prevent any of them from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

The Amendment has most recently been extended to September 30, 2018.

The applicability of Rohrenbacher-Blumenauer to adult-use cannabis businesses is not fully resolved as of the date of this SRIA. Attorney General Sessions has sent letters to several states reiterating that cannabis businesses could risk Federal enforcement actions if they do not adhere to the guidelines in the Cole Memo of 2013, which instructed Federal prosecutors not to devote public resources to pursuing Federal narcotics cases against state-law-compliant cannabis businesses in states with cannabis regulations. However, such business were responsible for adhering to certain guidelines in the Cole Memo; if they do not do so, they could be subjected to Federal narcotics enforcement supported by public resources. The language of the Cole memo was not limited to medicinal cannabis, whereas the more specific Rohrenbacher-Farr language limits its scope to the medicinal segment. Moreover, the Cole Memo has recently been rescinded.

In our economic modeling, we adopt what we believe to be the most prudent approach to sizing risk premia and other costs to California cannabis businesses that are affected by these issues, which is to observe the Federal law-related risk premia and costs that we believe to be internalized into medical cannabis businesses operating in California as of late 2017, including their access to the banking system and the capital markets.

The choice of a business to enter the medicinal segment vs. the adult-use segment could also be impacted in a meaningful way by Federal enforcement actions. To give an example, if the Department of Justice (DOJ) were to pursue a case against a single adult-use cannabis retail business in California, a large number of businesses could quickly abandon the adult-use segment for the medicinal segment. Given that the medicinal segment is inaccessible to out-of-state residents, such an event could have major economic consequences.

In the absence of any concrete evidence that DOJ enforcement patterns are changing, we assume that the threat of Federal enforcement against California cannabis businesses will not change substantially in the time interval contemplated by our analysis. Our simulation

results should be interpreted in the context of the uncertainties implied by this ambiguous situation.

3.2.2 International comparisons. Comparing the price of non-medicinal adult-use cannabis between countries demonstrates the workings of risk premiums more clearly. For instance, in Uruguay, where adult-use cannabis is decriminalized, the street price per ounce for medium-quality dried flower is about US\$172 (Marijuana Travels, 2016). In Germany, where adult-use cannabis is illegal but possession laws are generally not enforced, and where medicinal cannabis is legal, the street price for medium-quality dried flower is about US\$239 per ounce (Williams, 2016; Marijuana Travels, 2016). In China, where personal possession can land a first offender in prison for six months, the illegal-market price for one ounce of medium-quality dried flower is about \$696 per ounce (Hill, 2015; Marijuana Travels, 2016). (We recognize that there are other legal and economic differences influencing relative prices in these locations.)

3.3 Summary of costs

The data used to construct Tables 3.3 through 3.5 come from an aggregation of an informal AIC survey of cannabis retailers in California as of late 2017. To use these data to model initial industry costs and regulatory variation, we then convert these business costs into per-pound units. These per-pound cost estimates inform our other modeling efforts necessary to assess the impacts of regulations.

For our calculations of California retailing costs, we assumed a combined risk premium and net income of 16.67%, as shown in Table 3.3, which accounts for the discrepancy between our retail price estimate (\$3,600) and our estimate of the sum total of direct costs (\$3,000) based on the medicinal cannabis retailers we surveyed. The initial cost survey was conducted in late 2016, when the wholesale price was approximately \$1,565 and average of retail prices across store and products was approximately \$3,425. Subsequently, by the end of 2017, wholesale prices had fallen to approximately \$1,350 while retail prices rose to approximately \$3,600. To adjust our cannabis retailer base

operating cost estimates for the late 2017 market situation, we held our estimate of retail net income and risk premium constant at 16.67% while adjusting retailer sales, general, and administrative costs to account for new market conditions, particularly increased local compliance costs, based on new AIC data and anonymous follow-up interviews with industry participants.

These data are adjusted averages of the more detailed cost estimates that are provided by size category in Tables 3.4 and 3.5. Note that labor is the largest direct cost after raw materials.

Table 3.3. Average cannabis retailer base operating costs per pound, AIC estimates

Estimated average retailer direct operating costs per lb

| | |
|---|-------------------|
| Raw material supply cost ¹ | \$1,350.00 |
| Sales, general, and admin costs ² | |
| Labor costs (including benefits & HR) | \$940.00 |
| Rent, supplies, and overhead | \$320.00 |
| Community giving, education programs | \$20.00 |
| Legal, accounting, and local compliance costs | \$80.00 |
| Local permit fees and application preparation | \$40.00 |
| Public relations | \$70.00 |
| Delivery costs ³ | \$180.00 |
| Total retailer direct operating costs per lb | \$3,000.00 |

Average retail margins

| | |
|---|-------------------|
| Net income & risk premium (16.67%) ⁴ | \$600.00 |
| Total retailer revenue per lb | \$3,600.00 |

Note: All data averaged across a group of anonymous businesses from which AIC collected approximate current accounting information. Sales, general, and administrative costs in Table 3.4 were adjusted upward by an average of 20.4% to account for new supply costs and retail prices in 2017 market. Not all costs were adjusted equally, as relative cost components have also changed under 2017 market conditions that subjected many businesses to additional local regulatory costs as new municipal and county laws were passed. Giving and education costs were adjusted downward by \$20 before rounding. Local compliance and permitting costs were adjusted upward by \$20 each before rounding. Final numbers were rounded to the nearest \$10.

¹ Source: AIC estimate based on Cannabis Benchmarks wholesale cannabis weighted average, November/December 2017. See Section 3.1 for details.

² Source: Anonymized retailer internal accounting data collected by AIC.

³ Source: AIC vehicle delivery cost analysis. Retailers to customers only; does not include transportation between other licensees.

⁴ Source: AIC anonymized retailer accounting cost survey.

Table 3.4. Detailed operating costs per pound for four different representative retailer sizes

November 2016 estimates, without regulations in place. Note that these differ from the 2017 estimates in Table 3.3, which are adjusted upward to account for 2017 market conditions. Averages across a group of anonymous businesses.

| Retailer size categories: aggregates | Micro | Small | Medium | Large | All locations | |
|--|------------------|----------------------|----------------------|-----------------------|----------------------|-------------------|
| Total number of locations in category ¹ | 500 | 400 | 80 | 20 | 1,000 | |
| Category's share of total locations ¹ | 50% | 40% | 8% | 2% | 100% | |
| Aggregate volume in category (lb) | 155,000 | 320,000 | 100,000 | 125,000 | 650,000 | |
| Aggregate revenue in category | \$530 million | \$1.1 billion | \$340 million | \$430 million | \$2.4 billion | |
| Raw material margin per location | Micro | Small | Medium | Large | All locations | Averages |
| Volume per location (flower-equivalent pounds) ³ | 310 lb | 800 lb | 1,250 lb | 6,250 lb | 650,000 lb | 650 lb |
| Revenue per location ² | \$1.1 million | \$2.7 million | \$4.3 million | \$21.4 million | \$2.2 billion | \$3,424/lb |
| Raw material costs per location ³ | \$500,000 | \$1.3 million | \$2.0 million | \$9.8 million | \$1.0 billion | \$1,565/lb |
| Total raw material margin per location | \$600,000 | \$1.4 million | \$2.3 million | \$11.6 million | \$1.2 billion | \$1,859/lb |
| Fixed, labor, and administrative costs per location² | Micro | Small | Medium | Large | All locations | Averages |
| Labor costs (including benefits and human resources) | \$296,000 | \$540,000 | \$1,260,000 | \$5,550,000 | \$453 million | \$777/lb |
| Rent, supplies and other ops expenses | \$58,000 | \$139,000 | \$619,000 | \$3,053,000 | \$155 million | \$265/lb |
| Community giving, education Programs | \$15,000 | \$35,000 | \$52,000 | \$71,000 | \$23.6 million | \$40/lb |
| Legal, tax, and regulatory Compliance | \$16,000 | \$38,000 | \$110,000 | \$398,000 | \$33.0 million | \$57/lb |
| Permit fees and application Preparation | \$8,000 | \$18,000 | \$35,000 | \$63,000 | \$12.9 million | \$22/lb |
| Public relations | \$18,000 | \$45,000 | \$84,000 | \$225,000 | \$33.2 million | \$57/lb |
| Total fixed, labor, and administrative costs per location | \$411,000 | \$815,000 | \$2,160,000 | \$9,360,000 | \$710 million | \$1,218/lb |

Source: Anonymized retailer internal accounting data collected via AIC surveys and interviews.

Note: All numbers averaged across a group of anonymous businesses from which AIC collected approximate current accounting information. Estimates rounded to nearest \$1,000, \$10,000, \$100,000, \$1 million, \$10 million, or \$100 million, depending on magnitude. Numbers may not add or multiply exactly due to rounding.

¹ Represents number of discrete retail business premises. A single firm may operate several locations.

² Source: Anonymized retailer internal accounting data collected via AIC interviews and surveys. Does not include delivery costs or delivery employees.

³ Source: AIC estimates based on Cannabis Benchmarks Premium Reports wholesale price data and estimates from Era Economics.

Labor costs. Table 3.5 uses aggregate AIC accounting cost survey information to break down labor costs into categories. Wages average approximately \$18 per hour for non-manager employees and \$78 per hour for managers. Costs of labor are integrated into the retailer accounting costs used in our simulation model in Chapter 7, the results of Chapter 8 and the IMPLAN analysis reported in Chapter 9.

Table 3.5 Detailed retail labor cost breakdowns for four different representative retailer sizes, without regulations in place

November 2016 estimates, without regulations in place. Note that these differ from the 2017 estimates in Table 3.3, which are adjusted upward to account for 2017 market conditions. Averages across a group of anonymous businesses.

| Aggregates | Micro | Small | Medium | Large | All locations |
|---|---------------|---------------|---------------|----------------|----------------------|
| Total number of locations in category | 500 | 400 | 80 | 20 | 1,000 |
| Category's share of total locations | 50% | 40% | 8% | 2% | 100% |
| Aggregate volume in category (lb) | 155,000 | 320,000 | 100,000 | 125,000 | 650,000 |
| Aggregate revenue in category | \$530 million | \$1.1 billion | \$340 million | \$430 million | \$2.4 billion |
| Labor costs per location | Micro | Small | Medium | Large | Avg location |
| Avg employees per retailer ¹ | 6 | 10 | 15 | 60 | 9.4 |
| Revenue per location ¹ | \$1.1 million | \$2.7 million | \$4.3 million | \$21.4 million | \$2.4 million |
| Avg employees per \$1M revenues ¹ (incl managers + non-managers) | 6.1 | 3.7 | 3.5 | 2.8 | 3.9 |
| Avg revenue per employee ¹ | \$180,000 | \$270,000 | \$290,000 | \$360,000 | \$255,000 |
| Managers per retailer ¹ | 1 | 2 | 3 | 10 | 1.8 |
| Annual salary per manager ¹ (incl benefits & HR costs) | \$116,000 | \$126,500 | \$171,000 | \$355,000 | \$156,000 |
| Avg hourly wage per manager ¹ (assuming 2000 hrs per yr) | \$58 | \$63 | \$86 | \$178 | \$78 |
| Non-mgr employees per retailer ¹ | 5 | 8 | 12 | 50 | 7.7 |
| Non-mgr annual salary ¹ | \$36,000 | \$36,000 | \$36,000 | \$40,000 | \$36,500 |
| Avg hourly wage per non-mgr ¹ | \$18 | \$18 | \$18 | \$20 | \$18.25 |
| Total labor costs | Micro | Small | Medium | Large | Avg location |
| Avg total annual labor costs | \$296,000 | \$541,000 | \$945,000 | \$5,550,000 | \$550,000 |
| Avg annual salary per employee | \$49,000 | \$54,000 | \$63,000 | \$92,500 | \$58,500 |

Source: Anonymized retailer internal accounting data collected via AIC surveys and interviews.

Note: All numbers averaged across a group of anonymous businesses from which AIC collected approximate current accounting information. Estimates rounded to nearest \$1,000, \$10,000, \$100,000, \$1 million, \$10 million, or \$100 million, depending on magnitude. Numbers may not add or multiply exactly due to rounding.

¹ Does not include delivery employees, who are accounted for under “delivery costs.”

4. Late 2017 retail cannabis prices and price patterns in California

Public information on cannabis is scarce. Official data sources on current and historical prices, such as those published federally by the Bureau of Labor Statistics for most other common agricultural products, are unavailable. Estimates of prices are complicated because there are many different types of cannabis products sold in dispensaries. Furthermore, as with other consumer products, prices vary geographically and depend on the unit of quantity sold (for example, one-eighth-ounce sized packages versus one-ounce-sized packages). These complications mean that price data need to be handled carefully.

This chapter reports on a variety of information used to develop the representative price that is used in modeling and estimation. As an important component of this effort, AIC surveyed retailers in California from September 2016 through November 2017. The AIC survey collected price ranges (as highs and lows) by cannabis product, location, and by unit of quantity. We recorded whether the retailer was delivery-only and its customer rating. The majority of this chapter is devoted to discussing data collection methods, data descriptions, and data patterns. We also compare our survey information with price data available from other sources.

4.1 Product overview

Dried flower from the cannabis plant, which is generally inhaled through joints or pipes, is the dominant cannabis product at retail. Dried flower is sold in one-gram, eighth-ounce, quarter-ounce, half-ounce, and one-ounce packages and generally labeled by strain (e.g. “Sour Diesel,” “Blue Dream,” or “Citopamine”). Other information sometimes included on labels includes species (sativa, indica, or “hybrid,” indicating a sativa-indica cross-breed), strength (in active-ingredient concentration as measured by THC and CBD percentages), and occasionally branded quality or origin certifications.

According to informal industry sources and industry press reports, the fastest-growing portion of the California retail cannabis market is concentrated cannabis oil cartridges, which is vaporized and inhaled using battery-powered vape pens (hand-held devices similar to e-cigarettes). Cartridges contain oil concentrate (also known as “extract”) that is

generally extracted to THC levels between 50% and 75% and packaged in 500-milligram or one-gram cartridges. Other popular forms of concentrate include wax and shatter. Concentrates can also be consumed by “dabbing” or can be used in making edible cannabis products. Some concentrates at the top end of the market are now advertised in terms of aromatic compounds known as “terpenes,” whose functional effects are unclear.

Concentrates have been claiming increasing share in the cannabis market, especially for consumers willing to pay high prices. If the prices of the various products mentioned above are converted into prices per gram of THC in the package, edible cannabis products are the most expensive way of purchasing cannabis, followed by concentrates, and dried flower is the cheapest (Orens et al. 2015).

The AIC retail price survey, which is presented below, does not measure edible prices, but it confirms the finding by Orens et al. that THC in cartridge form sells for more than twice the price of THC in dried flower form. This reflects the additional costs of manufacturing and packaging, and in some cases it also reflects the margins of an additional business in the supply chain (the manufacturer who buys dried flower or oil and produces packaged cartridges or edibles).

See Section 5.3.1 for an explanation of the “flower equivalent” methodology we used to combine various forms of cannabis and estimate aggregate market prices and quantities.

4.2 Survey methods

AIC conducted a survey of medicinal cannabis retailers in California from late fall 2016 to late fall 2017. The main purpose of the survey was to learn about current distributions and other patterns of prices for medicinal cannabis.

Retailers are collectively representative of the varied demographics of California. We selected counties and cities to approximate the distribution of the medicinal cannabis retail outlets in the state and arrived at approximations of state-wide retail prices.

By using internet sources including WeedMaps, Leafly, Yelp!, Google Local, and retailers' own websites, we collected prices and other related information from each retailer. We called retailers when web information was unclear or insufficient. Data were collected five times. The first survey took place during a 60-day span ending on November 23, 2016. Although data collection began in late September, we recorded this as the November 2016 set of observations. We then surveyed prices again over 1-to-2-month periods ending in January 2017, March 2017, August 2017, and November 2017. In January 2017, March 2017, and August 2017 surveys, we tracked prices only at the retailers that had been initially included in the November 2016 survey.

We undertook an expanded November 2017 survey in order to update and refine our pre-regulation price estimates for this SRIA. For the expanded survey, we canvassed more than 2,500 medicinal cannabis retailers with their prices listed on WeedMaps, including both physical storefronts and delivery-only retailers across California. Our November 2017 survey covered a much wider geographical area than previous versions of the survey. For the calculations and simulation in this SRIA, we use the November 2017 weighted average of \$3,600 per pound. Details of this calculation and summary statistics for the November 2017 price survey data collection are in Table 4.1a.

In Tables 4.1b and following, in order to illustrate some of the nuances of high and low price movements in the year leading up to late 2017, we report price trends from our previous surveys between November 2016 and August 2017, which compiled prices at about 500 retailers in eight counties (Sacramento, Alameda, Santa Clara, Los Angeles, Fresno, Butte, San Diego, Kern) over the course of four observation periods.

We selected those eight counties to represent a broad mix of California-wide demographics. We note that any process of approximating state-wide averages with data

from a small subset of counties carries the inherent potential for systematic bias. However, average prices we observed at the 25000 retailers in the broader state-wide price survey of November 2017 do not appear to be out of line with the trends we observed in the eight-county sample during the four previous observation periods. Nonetheless, November 2017 averages cannot be directly compared to the previous four periods' averages, as the November 2017 data set is several times larger and represents a more complete picture of prices across California counties. In this SRIA, we use that November 2016 to August 2017 data purely for the purpose of illustrating trends over time.

4.3 Information collected

Our data set consists of several types of information for each retailer, including the retail location, characteristic (shop and/or delivery), cannabis retail prices, and the online ratings of the retailer. Retail location was categorized by county and city, and for storefront shops, we recorded the address. We also recorded website and phone number for most retailers.

Retailer characteristic: Some retailers operate their businesses without having a physical storefront with a physical address. In these cases, transactions are conducted online or via phone and the product is delivered to the consumer's home. For each retailer, we recorded whether the business is based out of a storefront retailer, whether the retailer delivers the products to consumers, or both.

Retail medicinal cannabis prices: Among the differentiated cannabis-based products sold, we chose three leading products that we judged to be most representative and comparable across different retail environments. In an initial pre-survey, we determined that one gram, one-eighth ounce, and one ounce are the three most common dried flower packages for sale at California cannabis retailers, and that the 500-milligram cartridge was the most common concentrate or extract package. We chose not to collect one-gram package prices due to their higher degree of variability within and between

locations. We thus collected prices for one-eighth-ounce and one-ounce dried flower and 500-milligram cartridges. As expected, we observed substantial quantity discounts per ounce for buying dried flower in one-ounce portions vs. one-eighth-ounce portions.

We collected maximum and minimum prices in each of these three product categories at each retailer. We chose this approach in part because many retailers have a price schedule with just two levels for eighth-ounce and one-ounce packages: basic and “top-shelf” prices. Some retailers had three to four price levels, but we rarely observed more than five. In the interest of simplicity, we collected two prices from each retailer: one “low” price, representing the lowest product in the price range for the given product, and one “high” price, representing the highest. Thus, the low and high prices for each of the three products generate six different prices in our data set.

As observed by Sifaneck et al. (2007) and discussed above, prices vary by characteristics and the quality level as perceived by consumers. It is important to note that perceived quality does not necessarily correspond to objective quality in terms of hedonic preferences. In the US wine market, a wide price spread between generic and premium prices appears to be stable even though the difference between generic-priced and premium-priced products are not readily distinguishable by wine consumers in blind taste tests (Goldstein et al. 2008), and beer consumers pay price spreads for premium brands whose physical properties they cannot readily differentiate (other than the label and branding; Almenberg et al. 2014).

For the cannabis marketplace, we collected data on both high and low prices to better understand the retail market, and we are thus able to observe consumer willingness to pay in two different perceived-quality categories. To construct our state-wide average retail price estimates, we used high and low prices for 1/8 ounce and 1 ounce dried flower, but not 500-gram cartridge prices (which were not available at a significant minority of retailers and varied considerably between products in THC levels, container (disposable vape pen vs. refillable vape pen with cartridge, refill cartridge, etc.). We report

500-gram cartridge prices in the survey of prices over time between November 2016 and August 2017 in Tables 4.1b and following.

4.4 Data overview

Table 4.1 reports the summary statistics of our survey data over the four survey periods. Out of about 2,500 retailers surveyed, approximately 20% of retailers conducted business from a storefront (with a physical address of the retailer; a small fraction of these storefronts also offered delivery), and 80% of retailers conducted business using a delivery service only.

Even though not all retailers report all four prices considered here, almost all retailers list the price of one-eighth ounce dried flower, which interviews consistently cite as the most frequently purchased item at retail (we do not yet have reliable data on the distribution of package sizes within dried flower purchases, however).

Comparing the high and low prices of dried flower for one-eighth ounce and one ounce, two main observations emerge. First, the high price is, on average, almost twice the low price. Second, there are considerable discounts for larger quantity. Our data indicate that the quantity discounts for buying an ounce of dried flower vs. buying 1/8 ounce of dried flower are as much as 25% for both high and low categories.

AIC's representative price of \$3,600 per pound dried flower that we used as an initial situation in our simulation analysis was derived with the following procedure. Our initial data consist of high and low prices in each sampled retailer for 1/8-ounce packages and full one-ounce packages. We did not include the manufactured products in this calculation because those products contain additional processing and packaging costs that add to the complexity of deriving the cannabis equivalent prices.

To calculate a representative high and low price per pound of flower-equivalent product, we used the statewide averages for each. The first step was to assign a volume share for

the low prices and high prices. We noted that for most consumer products, the highest-priced product has a much lower market share (by volume) than the low-priced product, meaning that the volume-weighted average market price falls below the mid-point between the generic and premium prices.

Guided by evidence from the beer and wine industries as explained in Section 4.8, we assumed that more low-end buyers would be likely to buy cannabis by the ounce. We constructed a weighted average of 1/8-ounce and 1-ounce high and low dried flowers prices using assumptions about aggregate quantity shares of each. We assumed relative quantity shares (by volume) of 20%, 10%, 60%, and 10% for 1/8-ounce low, 1/8-ounce high, 1-ounce low, and 1-ounce high prices, respectively. We used the statewide average by package size for high prices and low prices that we present in Table 4.1a to generate flower-equivalent-pound volume averages.

The November 2017 distributions of 1/8-ounce and 1-ounce dried flower prices, the weighted averages and AIC retail price estimate for late 2017, are presented in Table 4.1a. The weighted average price, which will be used as an aggregate representative retail price in our analysis, is calculated as \$3,600.

Table 4.1a. Summary statistics of AIC survey of cannabis retailers in California, Nov 2017
Advertised retail prices for dried cannabis flower in USD

| Summary statistics | 1/8 oz obs. | Pct | 1 oz obs. | Pct | | |
|--|------------------------|-------------------------|-----------|----------------------|-----------------------|-----------------|
| Storefront retailers | 517 | 20% | 487 | 21% | | |
| Delivery-only retailers | 2012 | 80% | 1847 | 79% | | |
| All retailers | 2529 | 100% | 2334 | 100% | | |
| Retail prices | 1/8 oz low | 1/8 oz high | Midpoint | 1 oz low | 1 oz high | Midpoint |
| Means | 30.7 | 50.7 | 40.7 | 177 | 305 | 241 |
| Modes | 35 | 50 | 42.5 | 200 | 280 | 240 |
| Medians | 30 | 50 | 40 | 160 | 300 | 230 |
| Assumed share of dried flower market | 20% | 10% | | 60% | 10% | |
| Weighted averages from November 2017 survey | 1/8 oz low Price/lb | 1/8 oz high Price/lb | | 1 oz low Price/lb | 1 oz high Price/lb | Weighted prices |
| Means | 3930 | 6490 | | 2832 | 4880 | 3622 |
| Modes | 4480 | 6400 | | 3200 | 4480 | 3904 |
| Medians | 3840 | 6400 | | 2560 | 4800 | 3424 |
| AIC working statewide weighted average retail price estimate, late 2017 | | | | | | 3600 |

Source: AIC cannabis price survey conducted in fall 2016 through summer 2017.

Changes over time in aggregate 1/8-ounce and 1-ounce dried flower prices between November 2016 and August 2017, as explained above, are presented in Table 4.1b. Comparing the distributions of low and high prices for dried flower indicates that low prices tend to be more clearly multi-modal than high prices for both 1/8 ounce and 1 ounce dried flower. We may infer some market structure information from these price distributions.

The following tables report averages from the group of 549 retailers in eight counties initially surveyed in November 2016. No new retailers were added to the survey in subsequent data collection periods. By August 2017, the fourth period, 395 retailers (72%) were still in the survey, and 154 (28%) had dropped out. Some of these closed or moved,

whereas some may have remained open but taken down their online profiles and advertised price information.

All prices in the following tables are reported in US dollars.

Table 4.1b. Average overall prices per oz of 1/8 oz and 1 oz flower over time, USD

| Product | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|-----------------------|--------|--------|--------|--------|
| Low 1/8 oz flower x8 | 225.0 | 219.1 | 218.7 | 222.8 |
| High 1/8 oz flower x8 | 435.8 | 432.6 | 430.9 | 409.0 |
| Low 1 oz Flower | 180.9 | 175.8 | 174.0 | 172.5 |
| High 1 oz Flower | 341.0 | 339.1 | 331.0 | 318.5 |
| Low aggregate | 204.1 | 198.4 | 987.7 | 198.8 |
| High aggregate | 391.0 | 388.0 | 383.5 | 365.8 |

Table 4.1c reports data from retailers with high and low values for 1/8 oz and 1 oz cannabis products across all four months observed. For clarity, this is noted by (ALL).

Table 4.1c. Average overall prices per oz of 1/8 oz and 1 oz flower over time (ALL)

| Product | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|-----------------------|--------|--------|--------|--------|
| Low 1/8 oz flower x8 | 234.4 | 227.1 | 226.6 | 223.7 |
| High 1/8 oz flower x8 | 460.3 | 455.9 | 442.2 | 423.1 |
| Low 1 oz flower | 177.9 | 176.7 | 178.5 | 173.2 |
| High 1 oz flower | 355.2 | 365.1 | 344.4 | 318.1 |
| Low both | 206.2 | 201.9 | 202.5 | 198.4 |
| High both | 407.8 | 410.5 | 393.3 | 370.6 |

The following tables include all data from the original cannabis data set, and “count” in tables indicates the number of observations used in calculating the average price. All prices are reported in US dollars.

Table 4.1d. Average low price and count for .5g cannabis cartridge over time by county

| County | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|---------------------------------|--------|--------|--------|--------|
| Sacramento Average | 28.7 | 28.3 | 29.4 | 27.5 |
| Sacramento Count | 36 | 40 | 41 | 42 |
| Alameda and Santa Clara Average | 27.8 | 27.7 | 26.6 | 28.6 |
| Alameda and Santa Clara Count | 20 | 18 | 18 | 15 |
| Los Angeles Average | 30.3 | 30.3 | 29.6 | 28.1 |
| Los Angeles Count | 120 | 126 | 104 | 114 |
| Fresno Average | 31.8 | 31.7 | 30.3 | 30.3 |
| Fresno Count | 22 | 26 | 25 | 23 |
| Butte Average | 35.9 | 35.9 | 35 | 32.7 |
| Butte Count | 11 | 11 | 15 | 13 |
| San Diego Average | 31.2 | 32.0 | 30.7 | 31.7 |
| San Diego Count | 84 | 70 | 78 | 69 |
| Kern Average | 29.6 | 29.9 | 30.1 | 27.3 |
| Kern Count | 23 | 19 | 27 | 21 |

Table 4.1e. Average high price and count for .5g cannabis cartridge over time by county

| County | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|---------------------------------|--------|--------|--------|--------|
| Sacramento Average | 46.1 | 43.2 | 43.5 | 41.0 |
| Sacramento Count | 36 | 40 | 41 | 42 |
| Alameda and Santa Clara Average | 45.0 | 49.8 | 49.2 | 48.1 |
| Alameda and Santa Clara Count | 20 | 18 | 18 | 15 |
| Los Angeles Average | 37.1 | 39.4 | 39.1 | 40.9 |
| Los Angeles Count | 121 | 126 | 104 | 114 |
| Fresno Average | 38.6 | 36.3 | 39.2 | 36.9 |
| Fresno Count | 22 | 26 | 25 | 23 |
| Butte Average | 47.3 | 47.3 | 43.2 | 39.2 |
| Butte Count | 11 | 11 | 15 | 13 |
| San Diego Average | 45.1 | 44.2 | 45.2 | 43.1 |
| San Diego Count | 84 | 70 | 78 | 69 |
| Kern Average | 35.4 | 36.7 | 39.2 | 35.6 |
| Kern Count | 23 | 19 | 27 | 21 |

Table 4.1f. Average low price and count for 1/8 oz cannabis flower over time by county

| County | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|-------------------------------|--------|--------|--------|--------|
| Sacramento Average | 28.2 | 27.1 | 26.6 | 26.4 |
| Sacramento Count | 66 | 58 | 56 | 55 |
| Alameda & Santa Clara Average | 27.4 | 28.9 | 29.8 | 28.5 |
| Alameda & Santa Clara Count | 21 | 19 | 19 | 19 |
| Los Angeles Average | 25.8 | 25.0 | 24.9 | 26.9 |
| Los Angeles Count | 242 | 213 | 185 | 152 |
| Fresno Average | 33.1 | 32.2 | 30.9 | 30.0 |
| Fresno Count | 46 | 43 | 37 | 36 |
| Butte Average | 29.3 | 29.3 | 28.8 | 27 |
| Butte Count | 22 | 22 | 21 | 15 |
| San Diego Average | 33.8 | 32.7 | 32.9 | 31.9 |
| San Diego Count | 109 | 91 | 87 | 84 |
| Kern Average | 21.1 | 20.5 | 21.9 | 21.9 |
| Kern Count | 43 | 36 | 35 | 34 |

Table 4.1g. Average high price and count for 1/8 oz cannabis flower over time by county

| County | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|-------------------------------|--------|--------|--------|--------|
| Sacramento Average | 50.7 | 52.5 | 50.8 | 52.6 |
| Sacramento Count | 66 | 58 | 56 | 55 |
| Alameda & Santa Clara Average | 54.8 | 54.7 | 59.1 | 54.8 |
| Alameda & Santa Clara Count | 21 | 19 | 19 | 19 |
| Los Angeles Average | 53.4 | 52.9 | 54.1 | 50.3 |
| Los Angeles Count | 243 | 213 | 185 | 152 |
| Fresno Average | 53.4 | 48.8 | 48.1 | 49.8 |
| Fresno Count | 46 | 43 | 37 | 36 |
| Butte Average | 47.3 | 47.3 | 49.5 | 47.7 |
| Butte Count | 22 | 22 | 21 | 15 |
| San Diego Average | 61.9 | 62.3 | 57.0 | 54.5 |
| San Diego Count | 109 | 91 | 87 | 84 |
| Kern Average | 52.1 | 52.9 | 52.2 | 45.1 |
| Kern Count | 43 | 36 | 35 | 34 |

Table 4.1h. Average low price and count for 1 oz cannabis flower over time by county

| County | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|-------------------------------|--------|--------|--------|--------|
| Sacramento Average | 169.0 | 169.8 | 162.1 | 165.0 |
| Sacramento Count | 62 | 56 | 51 | 51 |
| Alameda & Santa Clara Average | 216.5 | 196.9 | 201.9 | 204.2 |
| Alameda & Santa Clara Count | 20 | 17 | 19 | 17 |
| Los Angeles Average | 176.1 | 169.6 | 163.6 | 174.2 |
| Los Angeles Count | 223 | 195 | 166 | 141 |
| Fresno Average | 189.1 | 180.8 | 180.2 | 169.1 |
| Fresno Count | 39 | 38 | 32 | 31 |
| Butte Average | 162.1 | 162.1 | 164.2 | 149.2 |
| Butte Count | 17 | 17 | 18 | 12 |
| San Diego Average | 197.9 | 199.2 | 202.5 | 181.8 |
| San Diego Count | 101 | 90 | 84 | 81 |
| Kern Average | 160.1 | 143.3 | 151.0 | 144.8 |
| Kern Count | 32 | 27 | 27 | 27 |

Table 4.1i. Average high price and count for 1 oz cannabis flower over time by county

| County | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|-------------------------------|--------|--------|--------|--------|
| Sacramento Average | 326.4 | 334.0 | 332.7 | 336.4 |
| Sacramento Count | 62 | 56 | 51 | 51 |
| Alameda & Santa Clara Average | 367.5 | 353.8 | 358.8 | 363.3 |
| Alameda & Santa Clara Count | 20 | 17 | 19 | 17 |
| Los Angeles Average | 328.0 | 326.2 | 330.8 | 310.9 |
| Los Angeles Count | 223 | 195 | 166 | 141 |
| Fresno Average | 302.2 | 284.1 | 295.8 | 294.6 |
| Fresno Count | 39 | 38 | 32 | 31 |
| Butte Average | 291.8 | 291.8 | 285.8 | 308.3 |
| Butte Count | 17 | 17 | 18 | 12 |
| San Diego Average | 397.2 | 376.8 | 348.6 | 339.3 |
| San Diego Count | 101 | 90 | 84 | 81 |
| Kern Average | 340.3 | 415.2 | 326.3 | 266.1 |
| Kern Count | 32 | 27 | 27 | 27 |

Table 4.1j. Average price and count of each product by county

| County | .5g Cart Low | .5g Cart High | 1/8 oz Flower Low | 1/8 oz Flower High | 1 oz Flower Low | 1 oz Flower High |
|-------------------|--------------------|------------------|----------------------|-----------------------|--------------------|---------------------|
| Sacramento | | | | | | |
| Average | 28.5 | 43.3 | 27.1 | 51.6 | 166.9 | 332.1 |
| Sacramento Count | 159 | 159 | 235 | 235 | 220 | 220 |
| Alameda & Santa | | | | | | |
| Clara Average | 27.6 | 48.0 | 28.6 | 55.8 | 205.3 | 361.1 |
| Alameda & Santa | | | | | | |
| Clara Count | 71 | 71 | 78 | 78 | 73 | 73 |
| Los Angeles | | | | | | |
| Average | 29.6 | 39.1 | 25.6 | 53.0 | 171.1 | 324.8 |
| Los Angeles Count | 464 | 465 | 792 | 793 | 725 | 725 |
| Fresno Average | 31.0 | 37.7 | 31.7 | 50.2 | 180.4 | 294.1 |
| Fresno Count | 96 | 96 | 162 | 162 | 140 | 140 |
| Butte Average | 34.8 | 44.0 | 28.7 | 47.9 | 160.2 | 293.2 |
| Butte Count | 50 | 50 | 80 | 80 | 64 | 64 |
| San Diego Average | 31.4 | 44.4 | 32.9 | 59.1 | 195.6 | 367.4 |
| San Diego Count | 301 | 301 | 371 | 371 | 356 | 356 |
| Kern Average | 29.3 | 36.9 | 21.3 | 50.7 | 150.3 | 337.2 |
| Kern Count | 90 | 90 | 148 | 148 | 113 | 113 |

Table 4.1k. Average low and high prices for 1/8 oz and 1 oz flower by retailer type

| Retailer Type | 1/8 oz Low Price (US \$) | 1/8 oz High Price (US \$) | 1 oz Low Price (US \$) | 1 oz High Price (US \$) |
|-----------------------------|-----------------------------|------------------------------|---------------------------|----------------------------|
| Storefront only | 23.0 | 51.6 | 162.6 | 327.3 |
| Storefront only count | 985 | 985 | 903 | 903 |
| Delivery only | 33.1 | 55.7 | 192.4 | 340.2 |
| Delivery only count | 828 | 828 | 739 | 739 |
| Storefront & delivery | 30.4 | 54.4 | 180.1 | 341.9 |
| Storefront & delivery count | 53 | 54 | 49 | 49 |

Table 4.1l. Average low and high prices for 1/8 oz and 1 oz flower retailer type

| Retailer Type | 1/8 oz Low Price (US \$) | 1/8 oz High Price (US \$) | 1 oz Low Price (US \$) | 1 oz High Price (US \$) |
|-----------------------------|--------------------------|---------------------------|------------------------|-------------------------|
| Storefront only | 23.0 | 51.6 | 162.6 | 327.3 |
| Storefront only count | 985 | 985 | 903 | 903 |
| Delivery only | 33.1 | 55.7 | 192.4 | 340.2 |
| Delivery only count | 828 | 828 | 739 | 739 |
| Storefront & delivery | 30.3 | 54.4 | 180.1 | 341.9 |
| Storefront & delivery count | 53 | 54 | 49 | 49 |

The following tables are from the retailers with high and low values for 0.5g Cartridges, 1/8 oz, and 1 oz cannabis products across all four months observed. For clarity, this is notated by (ALL).

Table 4.1m. Average low price and count for .5g cartridge cannabis over time by county (ALL)

| County | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|-------------------------------|--------|--------|--------|--------|
| Sacramento Average | 27.6 | 26.7 | 27.6 | 24.3 |
| Sacramento Count | 21 | 21 | 21 | 21 |
| Alameda & Santa Clara Average | 25.9 | 25.64 | 26.6 | 29 |
| Alameda & Santa Clara Count | 11 | 11 | 11 | 11 |
| Los Angeles Average | 30.4 | 29.3 | 29.3 | 27.6 |
| Los Angeles Count | 51 | 51 | 51 | 51 |
| Fresno Average | 30.0 | 31.1 | 30.8 | 29.1 |
| Fresno Count | 9 | 9 | 9 | 9 |
| Butte Average | 36.3 | 36.3 | 39.0 | 33.1 |
| Butte Count | 8 | 8 | 8 | 8 |
| San Diego Average | 31.6 | 31.4 | 30.4 | 30.9 |
| San Diego Count | 44 | 44 | 44 | 44 |
| Kern Average | 30.0 | 30.0 | 30.0 | 29.4 |
| Kern Count | 9 | 9 | 9 | 9 |

Table 4.1n. Average low price and count for 1 oz cannabis flower over time by county (ALL)

| County | Nov-16 | Jan-17 | Mar-17 | Aug-17 |
|-------------------------------|--------|--------|--------|--------|
| Sacramento Average | 158.6 | 175.5 | 165.2 | 158.6 |
| Sacramento Count | 21 | 21 | 21 | 21 |
| Alameda & Santa Clara Average | 208.6 | 196.5 | 182.0 | 196.0 |
| Alameda & Santa Clara Count | 11 | 11 | 11 | 11 |
| Los Angeles Average | 182.4 | 170.0 | 167.2 | 175.9 |
| Los Angeles Count | 51 | 51 | 51 | 51 |
| Fresno Average | 208.9 | 189.4 | 178.9 | 179.4 |
| Fresno Count | 9 | 9 | 9 | 9 |
| Butte Average | 151.3 | 151.3 | 138.8 | 137.5 |
| Butte Count | 8 | 8 | 8 | 8 |
| San Diego Average | 202.8 | 212.8 | 204.4 | 188.9 |
| San Diego Count | 44 | 44 | 44 | 44 |
| Kern Average | 135.6 | 141.1 | 153.3 | 140.0 |
| Kern Count | 9 | 9 | 9 | 9 |

Table 4.1o. Average price and count for 1 oz cannabis flower over time by county (ALL)

| County | Mar- | | | |
|-------------------------------|--------|--------|-------|--------|
| | Nov-16 | Jan-17 | 17 | Aug-17 |
| Sacramento Average | 366.4 | 369.0 | 369.5 | 380.7 |
| Sacramento Count | 21 | 21 | 21 | 21 |
| Alameda & Santa Clara Average | 367.8 | 336.8 | 336.1 | 346.9 |
| Alameda & Santa Clara Count | 11 | 11 | 11 | 11 |
| Los Angeles Average | 351.6 | 351.1 | 353.1 | 327.6 |
| Los Angeles Count | 51 | 51 | 51 | 51 |
| Fresno Average | 321.7 | 329.4 | 342.8 | 321.1 |
| Fresno Count | 9 | 9 | 9 | 9 |
| Butte Average | 320.0 | 320.0 | 325.0 | 326.3 |
| Butte Count | 8 | 8 | 8 | 8 |
| San Diego Average | 391.3 | 390.6 | 358.4 | 356.5 |
| San Diego Count | 44 | 44 | 44 | 44 |
| Kern Average | 309.4 | 316.1 | 366.1 | 289.4 |
| Kern Count | 9 | 9 | 9 | 9 |

Table 4.1p. Average price and count of each product by county (ALL)

| County | .5g | .5g | 1/8 oz | 1/8 oz | 1 oz | 1 oz |
|--------------------------------|-------------|--------------|---------------|----------------|---------------|----------------|
| | Cart Low | Cart High | Flower Low | Flower High | Flower Low | Flower High |
| Sacramento Avg (84) | 26.5 | 44.8 | 23.1 | 53.7 | 164.5 | 371.4 |
| Alameda & Santa Clara Avg (44) | 26.8 | 48.5 | 27.9 | 53.9 | 295.8 | 346.9 |
| Los Angeles Avg (204) | 29.2 | 40.1 | 26.4 | 57.3 | 173.9 | 345.9 |
| Fresno Avg (36) | 30.2 | 36.9 | 28.0 | 52.9 | 189.2 | 328.8 |
| Butte Avg (32) | 36.2 | 49.5 | 27.8 | 55.3 | 144.7 | 322.8 |
| San Diego Avg (176) | 31.1 | 46.6 | 34.3 | 60.4 | 202.2 | 374.2 |
| Kern Avg (36) | 29.9 | 37.8 | 19.9 | 58.8 | 142.5 | 320.3 |

Note: Counts for each county are in parentheses

Table 4.1q. Average low and high prices and count by retailer type (ALL)

| Retailer type | 1/8 oz Low | 1/8 oz High | 1 oz Low | 1 oz High |
|------------------------------|------------|-------------|----------|-----------|
| Storefront only (312) | 23.7 | 54.2 | 165.4 | 341.4 |
| Delivery only (276) | 32.6 | 60.3 | 194.9 | 367.3 |
| Storefront and delivery (24) | 32.3 | 59.6 | 194.5 | 361.3 |

The following figures are based on the original AIC retail cannabis price survey data set from November 2016 to August 2017. These are not used in determining our final (Late 2017) retail price estimates in Table 4.1a, but rather as geographical context for considering the price differences between counties.

Figure 4.1a. Average low price of .5g cannabis cartridge by county

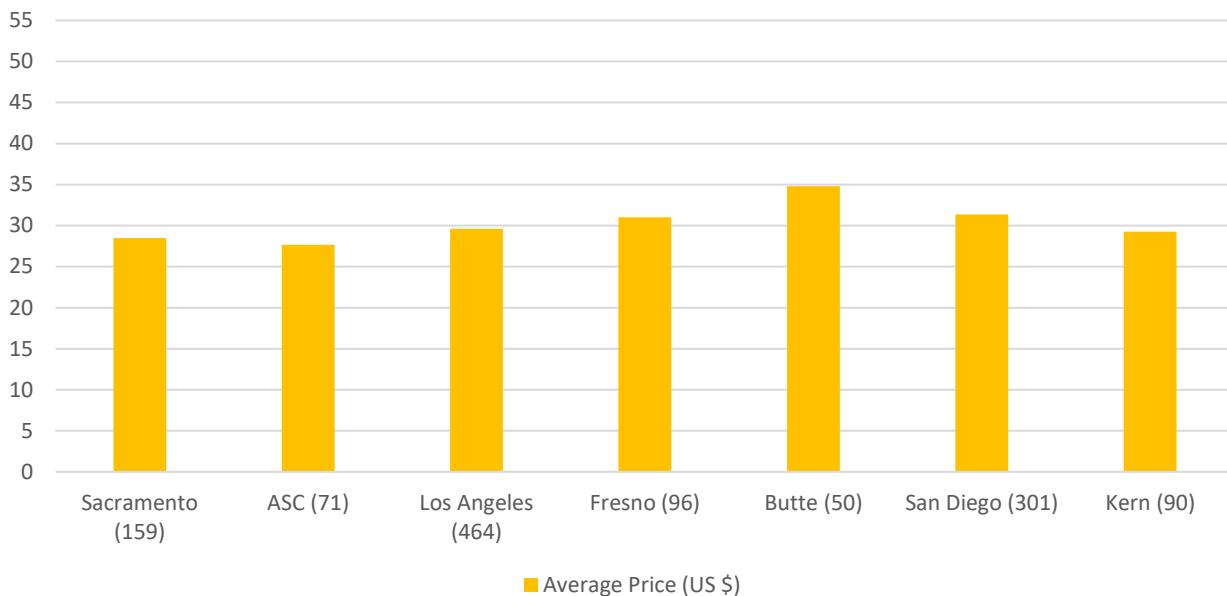


Figure 4.1b. Average high price of .5g cannabis cartridge by county

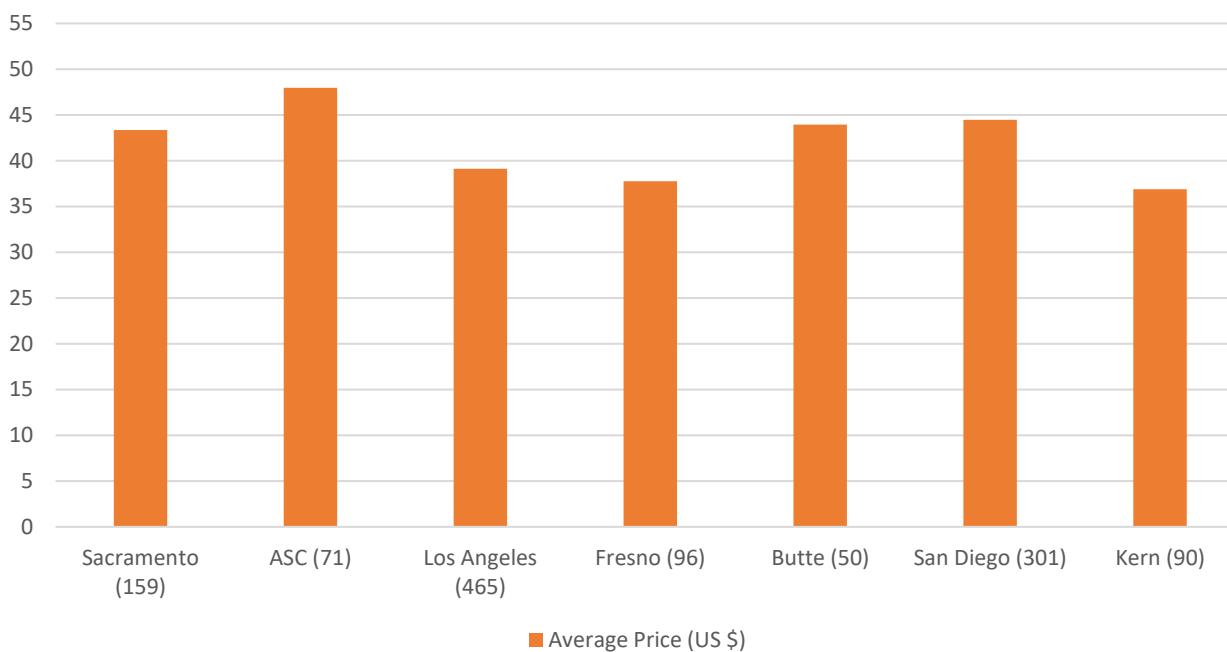


Figure 4.1c. Average low price of 1/8 oz cannabis flower by county

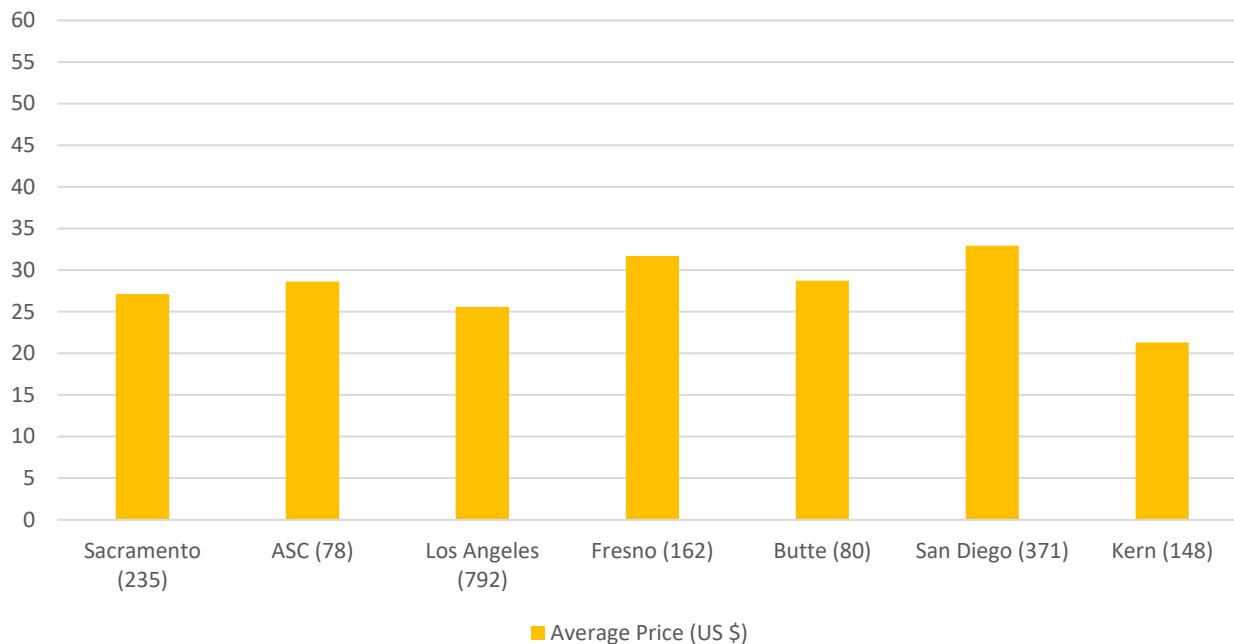


Figure 4.1d. Average high price of 1/8 oz cannabis flower by county

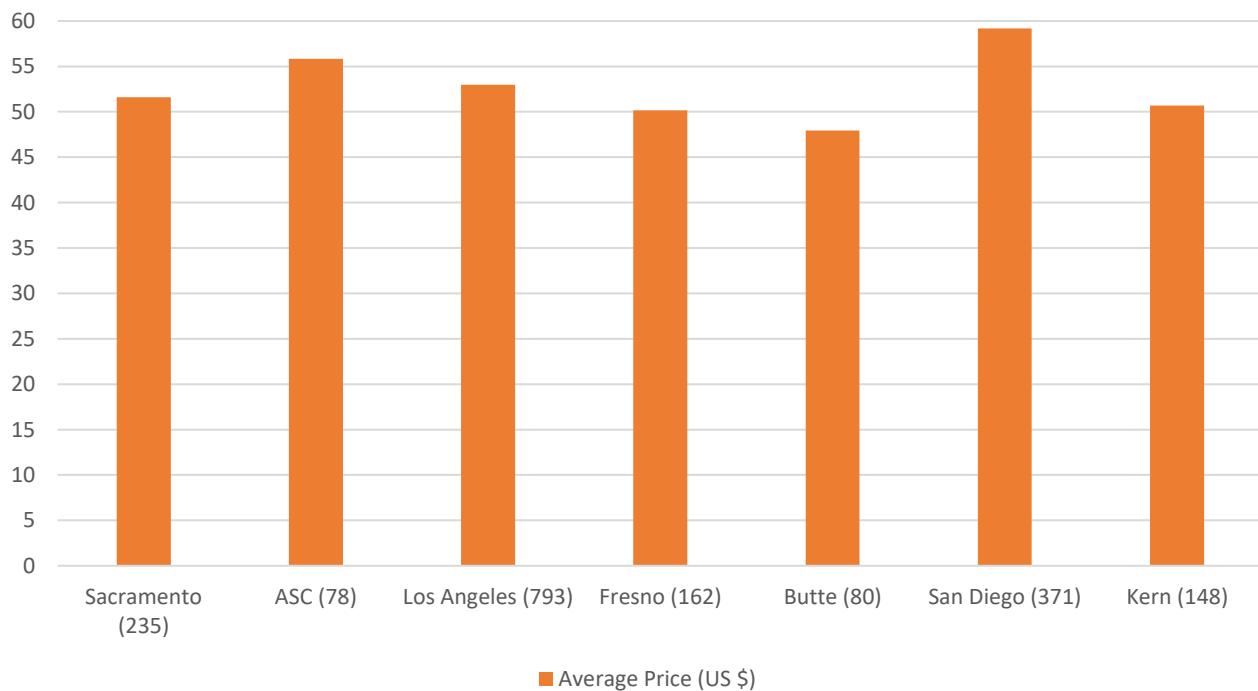


Figure 4.1e. Average low price of 1 oz cannabis flower by county

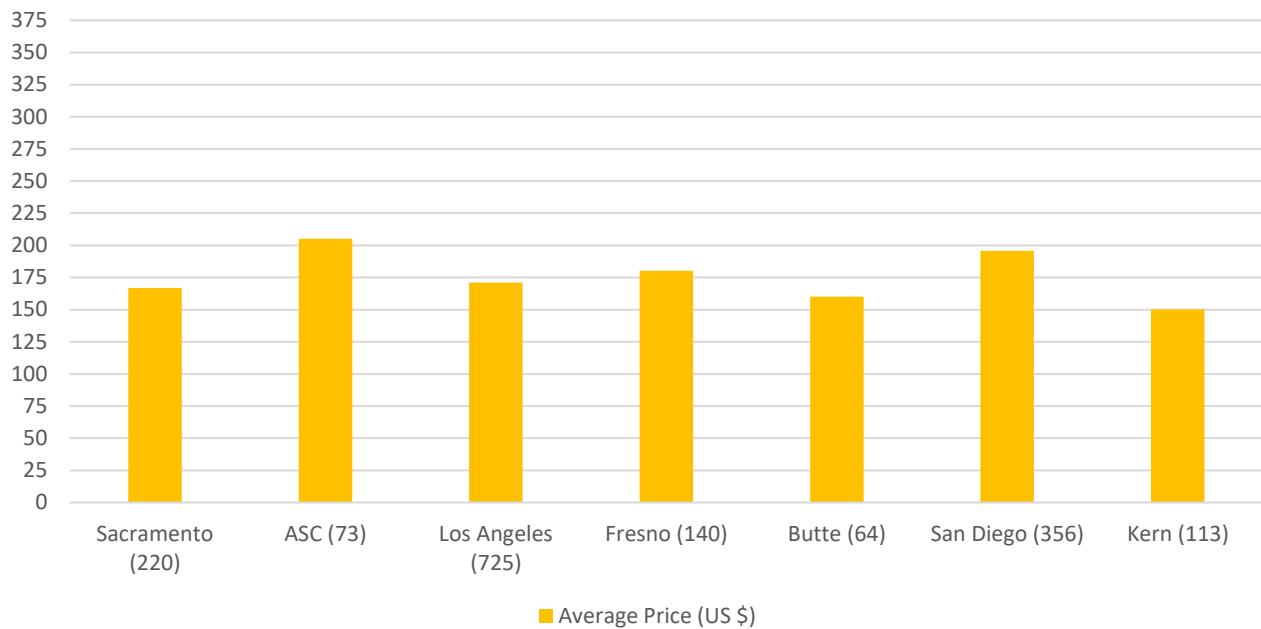


Figure 4.1f. Average high price of 1 oz cannabis flower by county

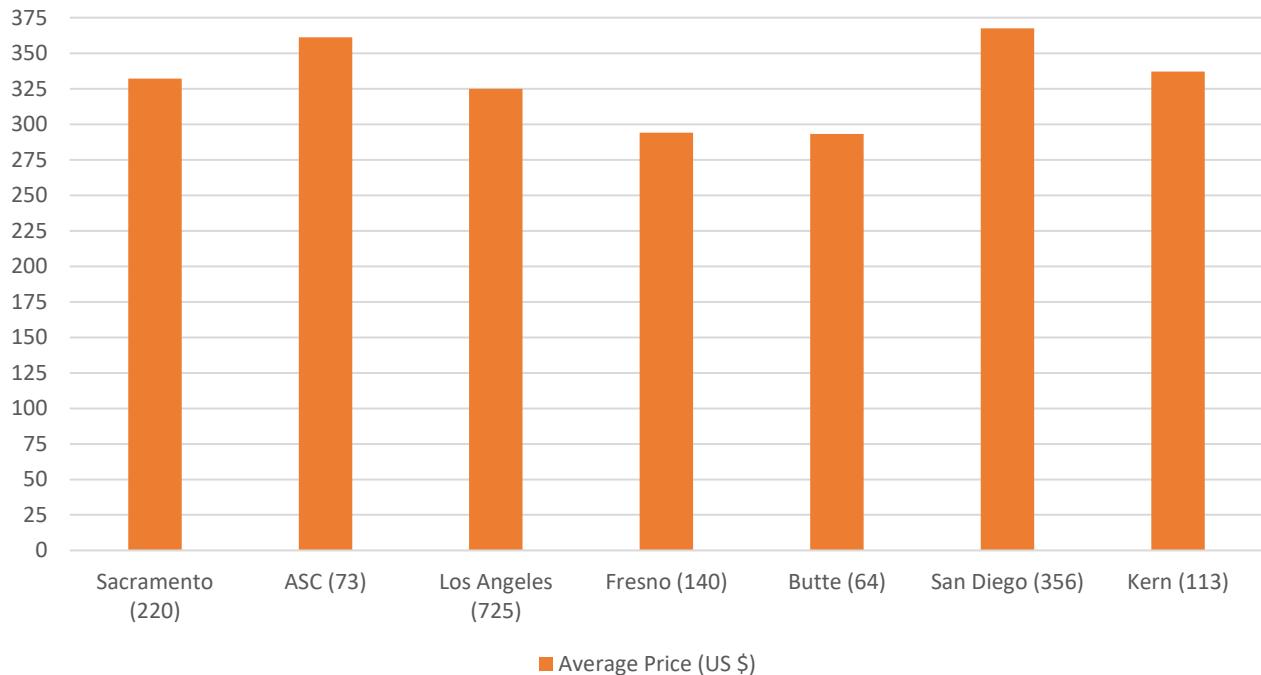


Figure 4.1g. Percent change in average low price of 1/8 oz cannabis flower over time in California, USD

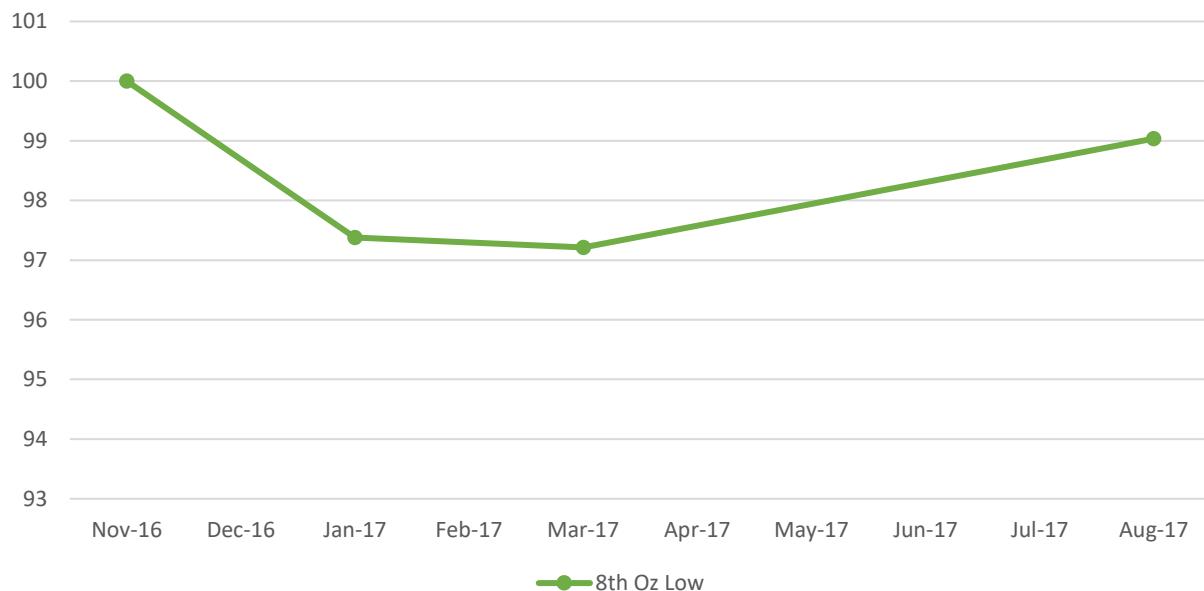


Figure 4.1h. Percent change in average high price of 1/8 oz cannabis flower over time in California, USD

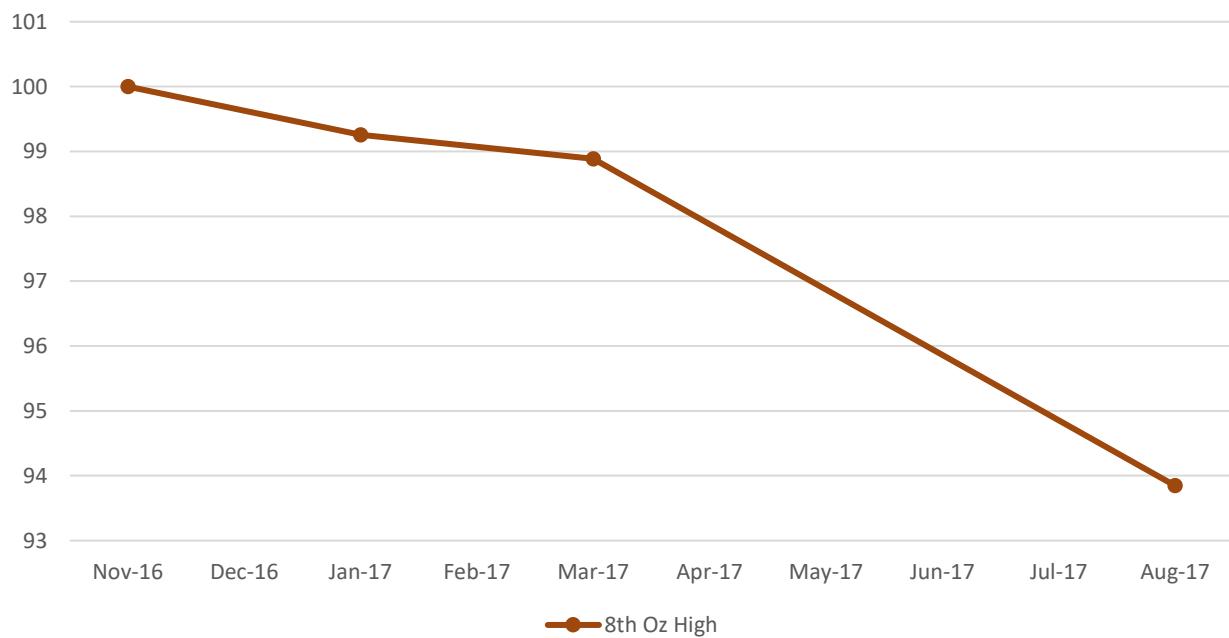


Figure 4.1i. Percent change in average low price of 1 oz cannabis flower over time in California, USD

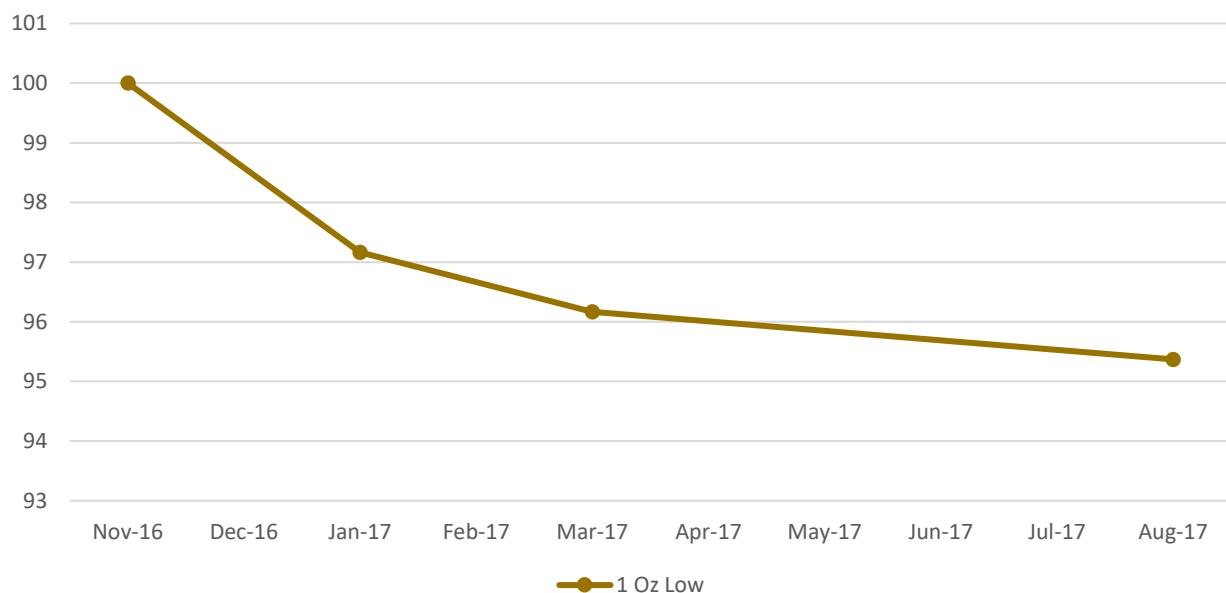


Figure 4.1j. Percent change in average high price of 1 oz cannabis flower over time in California, USD

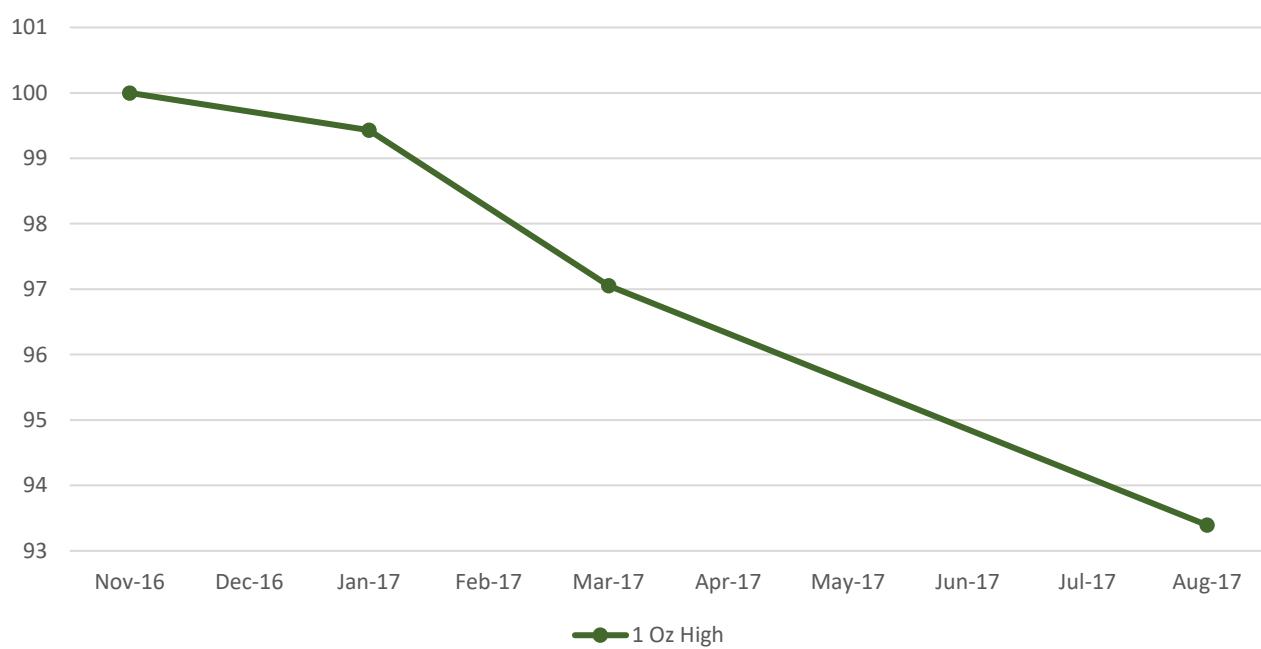


Figure 4.1k. Avg low price of 1/8 oz cannabis flower by retailer type, USD

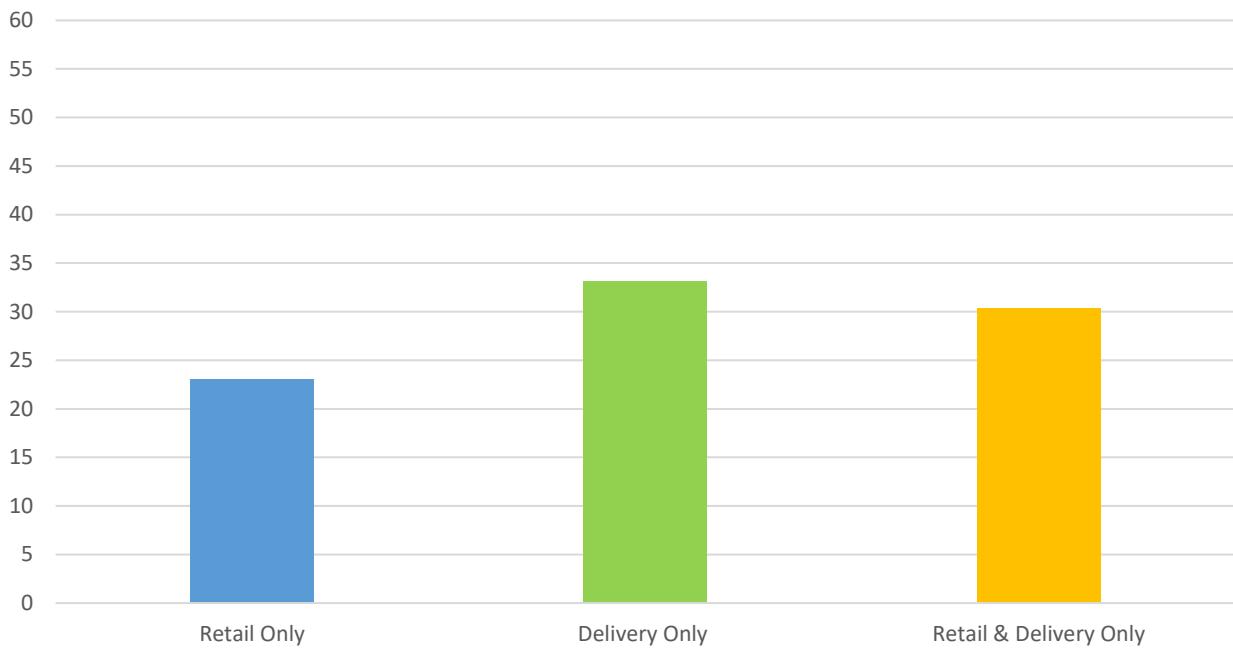


Figure 4.1l. Avg high price of 1/8 oz cannabis flower by retailer type, USD

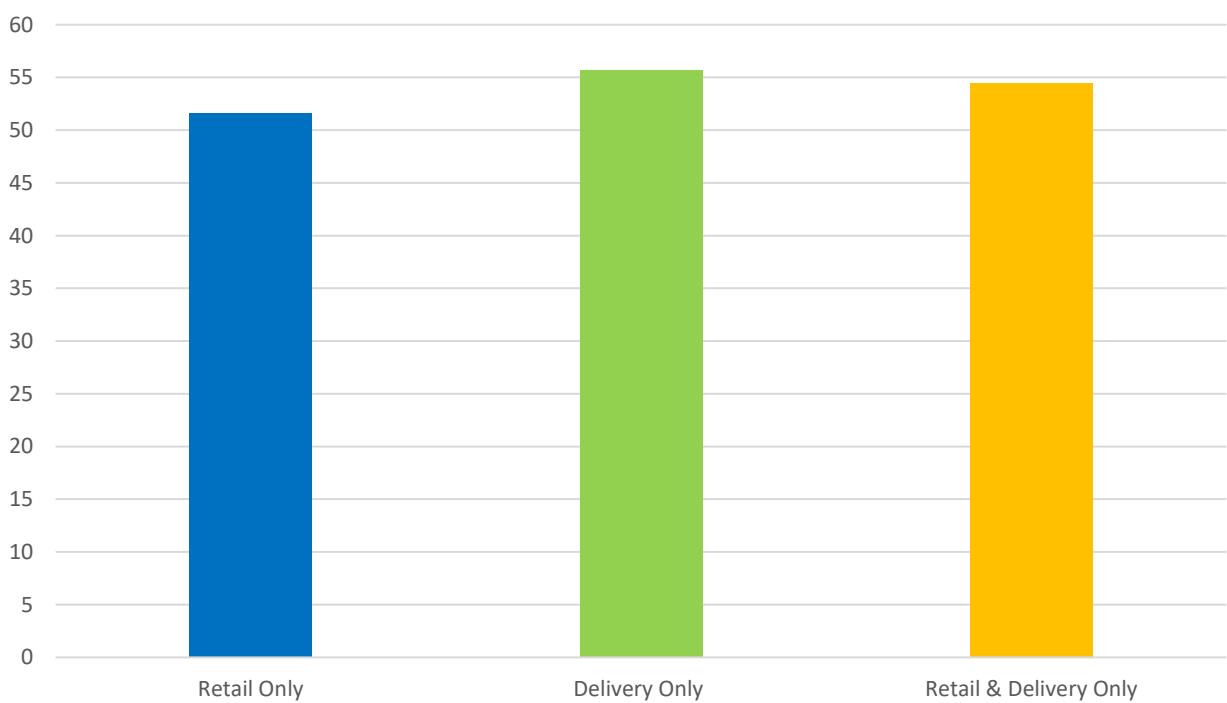


Figure 4.1m. Average low price of 1 oz cannabis flower by retailer type, USD

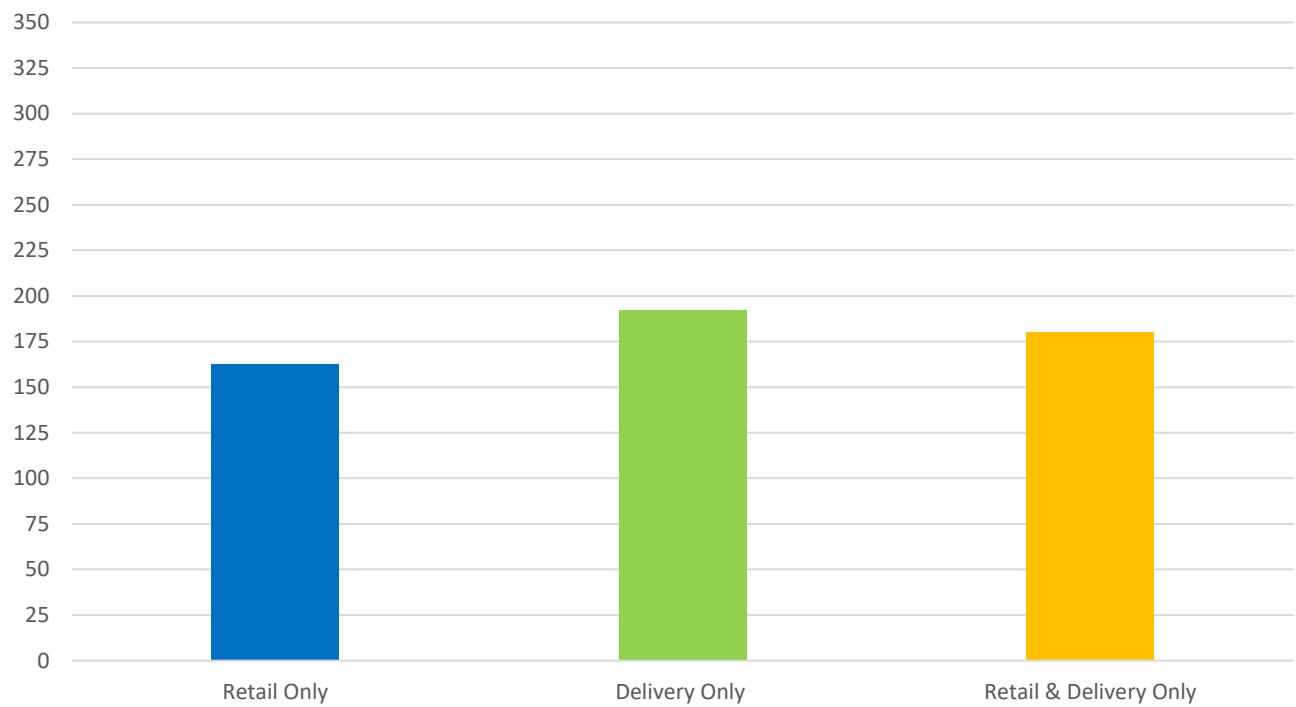
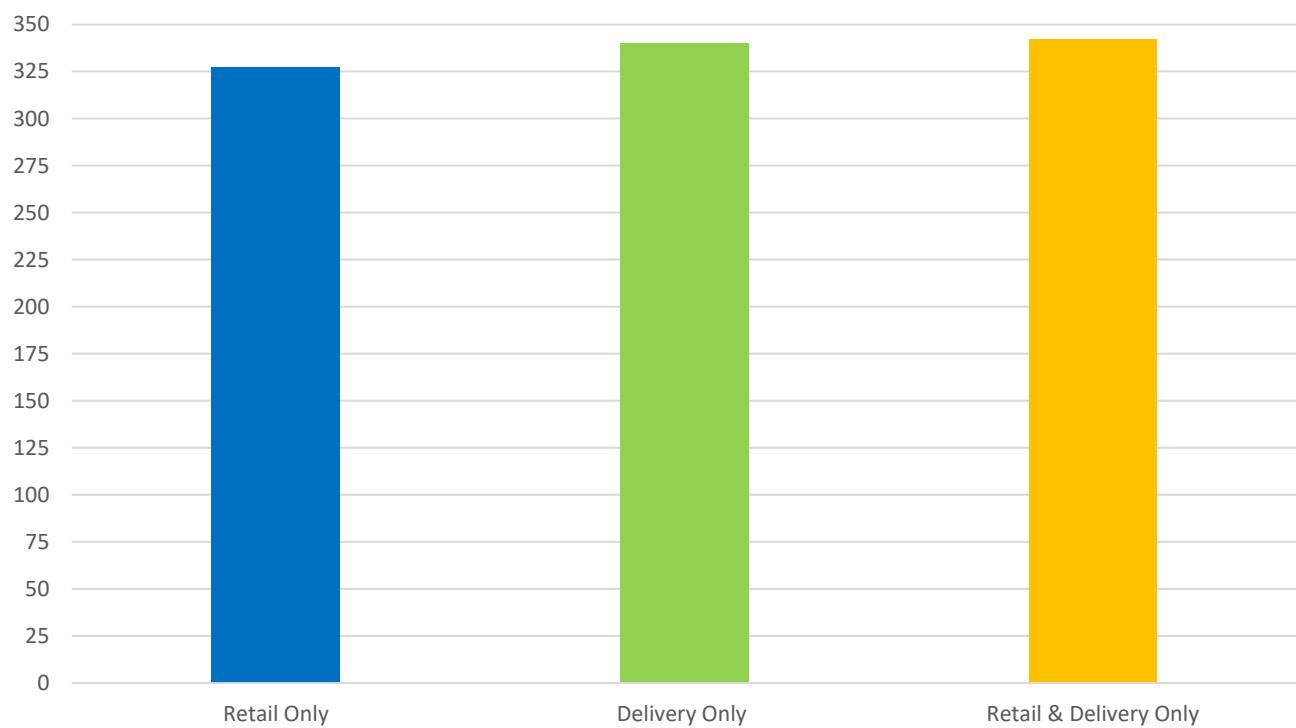


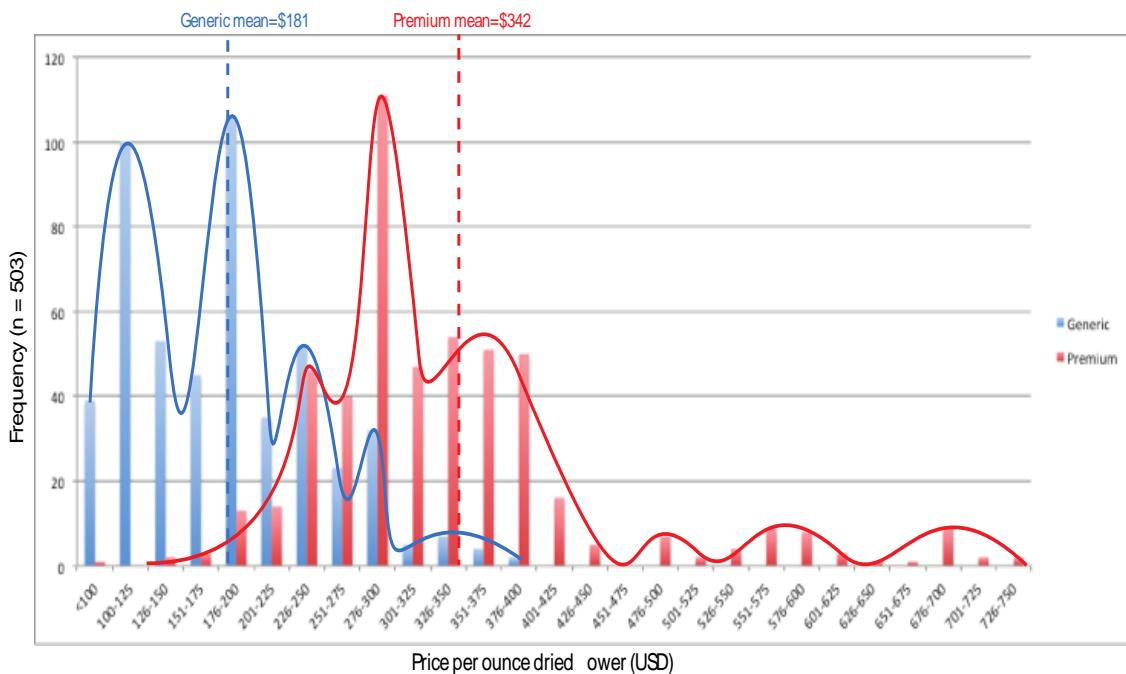
Figure 4.1n. Average high price of 1 oz cannabis flower by retailer type, USD



4.5 Complexities in price distributions

Here we examine complexity in price distributions using one-ounce dried flower prices. The analysis below begins by censoring the data into price categories with a range of \$25 each, which yields a multi-modal frequency distribution of prices that is not easily described by conventional distribution forms. Here we use our initial (November 2016) AIC price survey data collection period with a sample of 494 1-ounce “high” and “low” retail prices.

Figure 4.2. Distribution of 1 ounce retail dried flower prices, California, Nov 2016



Source: AIC cannabis price survey conducted in fall 2016.

For the low-priced category, we see two modes, local modes of \$175 to \$200 per ounce and \$100 to \$125. What we are likely seeing at the \$100 and \$200 levels is quality differentiation: normal-potency dried flower at the higher primary mode versus lower-potency “shake” or “schwag” at the lower secondary mode. The mean price per ounce across retailers for the low prices is \$181, and the mass of the distribution is skewed to the left of center.

For the high-price observations, the frequency distribution has a modal price of \$276 to \$300. The mean of the high prices per ounce is \$342, and the mass of the distribution is skewed to the left of center with a long, stretched tail on the right side of the distribution. One interpretation of the price distributions is that neither consumers nor sellers know quality. Another is that there are many quality classes of cannabis products, which have not been standardized.

The multi-modality of generic markets may indicate more variability in the quality of products even within the generic category, or may suggest the influence of other key factors relative to the single-modal premium market products.

4.6 Concentration premium effects in the California retail cannabis market

To get a broad picture of the relationship between prices and product THC levels, in late 2016, we solicited a separate sample of 106 price-THC pairs from a stratified sub-sample of eight retailers scattered across the state. We then partitioned the data into nine price categories and created an ordinal “price category” variable. We then calculated the mean THC measurements of products falling into each of these nine categories, which allowed us to observe a smoothed version of the price-THC relation in the sub-sample for which THC was reported. We note a tendency for price to rise with THC. Table 4.2 displays the low and high prices for each of the eight sub-sample retailers.

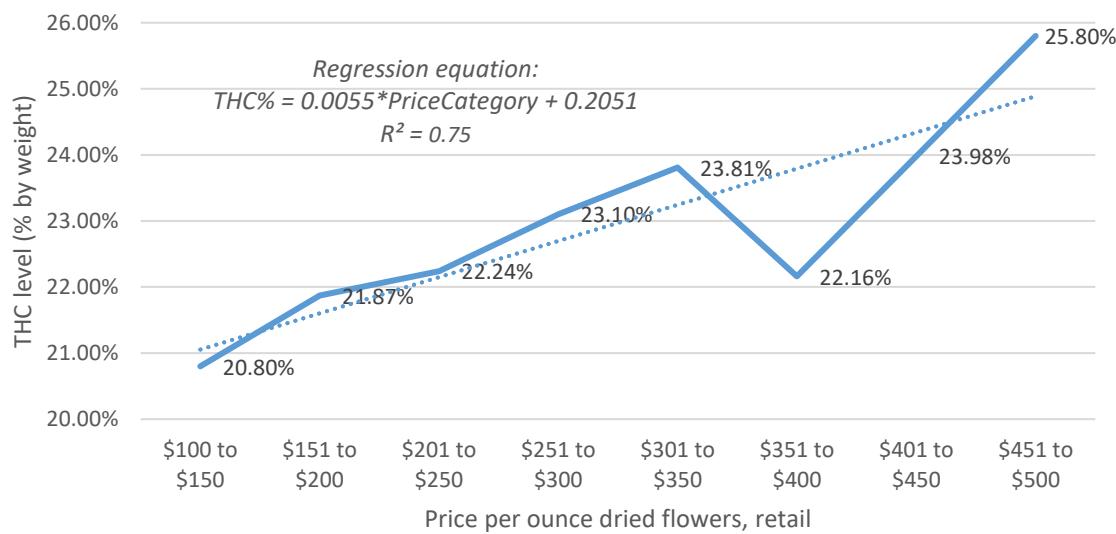
Table 4.2. Summary statistics, sub-sample

| Price range | Products | Mean THC level |
|--------------------|-----------------|-----------------------|
| \$100 to \$150 | 2 | 20.80% |
| \$151 to \$200 | 7 | 21.87% |
| \$201 to \$250 | 14 | 22.24% |
| \$251 to \$300 | 38 | 23.10% |
| \$301 to \$350 | 27 | 23.81% |
| \$351 to \$400 | 10 | 22.16% |
| \$401 to \$450 | 0 | N/A |
| \$451 to \$500 | 5 | 25.80% |
| \$501 to \$550 | 1 | 48.30% |

Source: AIC cannabis price survey conducted in fall 2016.

Next, we considered a price-category linear regression that turns each of these nine price categories into an ordinal variable from 1 to 9 (i.e., we predicted average THC level given a price category, coding price category as an ordinal variable from 1 to 9). This regression yields a coefficient that estimates the price effect related to category. This price-category coefficient was estimated as 0.0055, meaning that moving up 1 unit on the 1-to-9 price-category scale, which corresponds to an increase in price of \$50 per ounce of dried flower, is associated with the expected average THC level of all products in the price category rising by approximately 0.5%. We have not weighted this regression by sample size in each category, and we ignore one outlying category with only one observation of a single product that had almost double the THC of any other product in the sample. Results are shown in Figure 4.3 and Table 4.3.

Figure 4.3. Price category-THC relationship, sub-sample



Source: Sub-sample from AIC cannabis price survey conducted in fall 2016.

Table 4.3. Low and high prices and THC levels

| Retailer | Low Price | THC Level | High Price | THC % | Price spread | THC spread |
|--------------|--------------|---------------|--------------|---------------|--------------|------------|
| #1 | \$360 | 19.00% | \$480 | 25.80% | \$120 | 6.80% |
| #2 | \$250 | 21.10% | \$380 | 30.50% | \$130 | 9.40% |
| #3 | \$199 | 22.80% | \$350 | 28.46% | \$151 | 5.66% |
| #4 | \$240 | 21.40% | \$330 | 23.72% | \$90 | 2.32% |
| #5 | \$120 | 21.50% | \$400 | 22.67% | \$280 | 1.17% |
| #6 | \$285 | 15.65% | \$360 | 17.70% | \$75 | 2.05% |
| #7 | \$200 | 15.90% | \$340 | 23.70% | \$140 | 7.80% |
| #8 | \$140 | 20.10% | \$280 | 26.48% | \$140 | 6.38% |
| Means | \$224 | 19.70% | \$365 | 24.90% | | |

Source: Sub-sample from AIC cannabis price survey conducted in fall 2016.

4.8 Quantity-weighted average prices tend to be well below midpoints and medians: evidence from beer and wine

We examined the price distribution of beer and wine to help confirm that market volumes tend to be higher for products that sell in the lower price categories, such that average market prices tend to below midpoint or median prices.

Most product categories are composed of goods with varying attributes that sell for different prices and in different volumes. To determine the weighted average price of a good in a particular category, we must know both the volume and price of the good. Beer and wine sales in the United States are examples of price diversity within a broad category.

Below is a chart of retail beer sales in the United States by volume and total dollar for the first 11 months of 2016. These data are from based on the market surveys conducted by IRI (a firm specialized in retail surveys including scanner data). The unpublished summary in Table 4.4 was supplied to us courtesy of the National Brewers Association. Volume units are in cases (24 cans of 12 ounces per container, or 288 ounces per case).

Table 4.4 Distribution of beer prices and volumes by price category

| Beer segment | Retail sales (\$ millions) | Share of Category | Volume Sales (millions of cases, 24 x 12 oz) | Volume Share of Category | Retail Price (\$/case) |
|------------------------|--------------------------------------|--------------------------|---|---------------------------------|----------------------------------|
| Domestic sub-premium | \$4,788 | 16% | 299 | 24% | \$16 |
| Domestic premium | \$11,699 | 40% | 567 | 45% | \$21 |
| Import | \$5,192 | 18% | 173 | 14% | \$30 |
| Craft | \$3,224 | 11% | 89 | 7% | \$36 |
| All and Average | \$29,248 | 100% | 1,272 | 100% | \$23 |

Source: National Brewers Association, 2016.

The average of the lowest price per case (\$16.00) and the highest price per case (\$36.08) is \$26.04. However, the actual weighted average case price is \$22.99, approximately 13% below the average of the high and low prices.

Table 4.5 is from the 2013 Gomberg-Fredrikson Report of *wholesale* wine shipments from California wineries to wholesalers in the United States. Retail wine prices differ by category more than do beer prices. Some wines retail under \$3 per bottle, while others retail at well over \$100 per bottle. This price diversity is reflected in the Gomberg-Fredrikson data, which show an average wholesale case price of \$51 but a range of \$20 to \$128 per case.

Table 4.5 Distribution of wine prices and volumes by price category, 2013

| Wine segment (750-mL bottle price) | Wholesale Dollar Sales (\$ millions) | Share of Category | Volume Sales (millions of cases, 12 x 750 ml) | Volume Share of Category | Wholesale Price (\$/case) |
|--|--|--------------------------|--|---------------------------------|-------------------------------------|
| <= \$3 | \$958 | 9% | 47 | 22% | \$20 |
| >\$3-\$7 | \$2,309 | 21% | 71 | 34% | \$33 |
| >\$7-\$14 | \$3,961 | 37% | 64 | 31% | \$62 |
| >\$14 | \$3,573 | 33% | 28 | 13% | \$128 |
| Totals/averages | \$10,801 | 100% | 210 | 100% | \$51 |

Source: Gomberg-Fredrikson Report (2013), reporting data from wholesale wine shipments from California wineries to wholesalers in the United States. Data provided by courtesy <https://www.gfawine.com/products/gfr/>

4.9 Illegal cannabis prices in California

Illegal cannabis prices, which are not publicly advertised or displayed in storefronts, are difficult to measure than cannabis prices in the unregulated medicinal cannabis market.

Illegal prices are also known to vary more than legal prices, and price discrimination is common, making the task of estimating illegal prices even more difficult.

One of the few resources available that surveys California illegal cannabis prices side-by-side with legal medicinal prices, so that the difference between the two can be observed, is Budzu (budzu.com), a cannabis website with a crowd-sourced dried flower price database that collects anonymously reported legal and illegal prices from many users. The submission form asks users to submit their country, state, city, price, quantity, quality (rated from one to five stars), and source (“a dispensary,” i.e. retailer, or “the street”).

Although the site does not disclose the exact number of data points used, we estimated (based on the length of the data collection time period and the number of average submissions per week) that the averages were derived from approximately 1,000 California cannabis price data points. Voluntary self-reported data from user-generated sites can be unreliable for several reasons, of which selection bias may be the biggest problem.

The AIC analysis thus used the Budzu data primarily for observing the ratio of legal to illegal prices, rather than absolute prices. We disregarded quality ratings and averaged all quality categories. We included data for 1/8-ounce and 1-ounce quantities (the same as in our AIC retail survey), and we used simple averages to aggregate data. A summary of Budzu’s averages for “dispensary medical” and “street recreational” is shown in Table 4.6.

Table 4.6 Crowdsourced California legal and illegal dried flower prices, USD

| | <i>Medicinal (legal) prices</i> | | <i>Street (illegal) prices</i> | | |
|-----------------|--------------------------------------|--------------------------|--------------------------------------|--------------------------|----------------------------|
| <i>Quantity</i> | <i>Avg across all quality levels</i> | <i>Range of averages</i> | <i>Avg across all quality levels</i> | <i>Range of averages</i> | <i>Legal price premium</i> |
| 1/8 oz | \$43.43 (\$5,559/lb) | \$40.30– \$46.67 | \$28.42 (\$3,637/lb) | \$23.18– \$32.08 | 53% |
| 1 oz | \$203.20 (\$3,251/lb) | \$180.74– \$221.78 | \$136.32 (\$2,181/lb) | \$111.07– \$158.73 | 49% |
| Overall average | \$4,405/lb | \$2,891– \$5,973 | \$2,909/lb | \$1,777– \$4,106 | 51% |

Source: Budzu.com

In sum, the average price premium for illegal cannabis in the Budzu data from these two quantity types was 51% above the legal (medicinal) price.

In order to provide another point of reference to counter-balance the Budzu data, we also conducted a brief price survey amongst five representative illegal cannabis consumers from different demographic groups around the state. Consumers agreed to provide their age, sex, location, and profession, under the condition that their names would remain anonymous. Their reported illegal cannabis prices appear in Table 4.7.

Table 4.7 Illegal dried flower prices reported by representative California buyers

| Consumer | Price | Quantity | Price/lb |
|--|--------------|-----------------|-----------------|
| #1 (age: 22, dairy technician, Sonoma) | \$2,000 | 1 lb | \$2,000/lb |
| #2 (age: 45, lawyer, Santa Rosa) | \$220 | 1 oz | \$3,520/lb |
| #3 (age: 38, architect, San Francisco) | \$800 | 1 lb | \$800/lb |
| #4 (age: 32, graphic designer, Pasadena) | \$150 | 1 oz | \$2,400/lb |
| Overall average | | | \$2,205/lb |

Source: AIC interviews

Noting the obvious shortcomings of a survey with such a small sample size, the average price premium of legal (medicinal) cannabis reported by these four broadly representative consumers, compared with the estimate from our AIC retail price survey of \$3,600 per pound for legal (medicinal) cannabis, at 63% over the illegal average of \$2,205—somewhat higher than the Budzu average premium of 51%.

For the purposes of our market simulations, we assumed a 54% legal premium (in between the estimates generated by the two methods above, but much closer to the larger-sample Budzu estimate) and assumed an illegal cannabis price of \$2,340 per pound, or 65% of the estimated retail price of \$3,600 per pound.

5. Estimates of California cannabis market size and segmentation before and after the introduction of taxation, adult-use sale legalization, and regulations outside the Bureau's authority

In this chapter we evaluate the California retail cannabis market. We first clarify our framework for constructing and modeling the cannabis market and its segments. We then draw on the data and market research that is presented in Sections 5.3 and 5.4 below to construct estimates of prices and quantities in the late 2017 California cannabis market, before any state cannabis regulations went into effect.

5.1 Market segments

We look at a snapshot of the November/December 2017 market to produce our estimates of the late 2017 California cannabis market. This November/December 2017 cannabis market was divided into two parts, which we call “segments”: the legal medicinal cannabis segment, which as of late 2017 was regulated only at the county and municipal level and not at the state level (hereafter denoted as “medicinal,” or “m” in the notation used in Appendix Chapter 7); and the illegal non-medicinal cannabis segment, which, by construction, was unregulated (hereafter denoted as “illegal,” or “i” in the notation used in Appendix Chapter 7).

The terms “legal” and “illegal” can be confusing, especially in the context of cannabis, which is illegal under Federal law and seems likely to remain so in 2018 and beyond. In the present discussion, by “legal,” we mean to refer only to the status of sales in the segment under California state law at the specific time to which the discussion applies. Even this determination can be unclear, as for example some cannabis sellers in late 2017 were operating in observance of some parts of SB 420 and the Brown Guidelines and others were not.

We handle such confusion simply by constructing our “medicinal” cannabis segment broadly to include all cannabis that is sold upon the presentation and verification of a

medicinal recommendation, including but not limited to sales at storefront retailers, retail delivery services, and patients' collectives. We use the term "illegal" segment to refer to the rest of cannabis sales in the late 2017 market. This segment includes all cannabis sold to any consumers (whether medicinal patients or non-patients) via non-medicinal channels, including street dealers, non-medicinal delivery services, and direct grower-to-consumer sales.

In Section 5.3, we survey a range of available data describing the market through November/December 2017. We state our assumptions and make estimates of prices and quantities in the legal medicinal cannabis segment, the illegal non-medicinal cannabis segment, and the total California cannabis market in the late 2017 situation. Because many of our data sources are monthly indicators, and assuming that market prices will take more than three weeks to reflect the effects of partial adult-use decriminalization due to Proposition 64, we collected measurements (including our AIC retail price survey) through mid-December 2017.

As is detailed in Section 5.3, we agree with other industry analysts in estimating that the majority of cannabis sold in the marketplace as of late 2017 went through illegal channels. Specifically, we estimate that the illegal segment comprises 75% by weight (in flower equivalent; see Section 5.3.1 for explanation of units and conversion methodology) of the late 2017 cannabis market, and that the medicinal segment comprises 25% by weight.

5.2 Effects of changes to market segments

Before proceeding to describe some data of the situation in late 2017, we briefly explain how these estimates will be used in the simulation model that is detailed in Chapter 7. The situation with regulations in place will be different from the 2017 situation in three major ways: sale of all legal cannabis will be taxed, the sale of adult-use cannabis will be legalized, and the sale of all legal cannabis will be regulated by several jurisdictions and agencies. In order to separate out the respective economic impacts of taxation of all cannabis, legalization of adult-use cannabis sale and non-Bureau regulations (taken

together) from the economic impacts of proposed Bureau regulations, we apply the changes to our model in two separate steps, estimating at each step the new prices and quantities generated by the model.

We also must make a number of additional assumptions to simulate impacts, including estimates of price elasticities of demand for each segment, supply elasticities and the expected cost (supply) and demand shifts that are assumed to be caused by the two major changes. With these assumptions we are then able to make projections of the effects of each of the major changes on prices and quantities in the medicinal ("m") segment, in the illegal ("i") segment, and in a new legal adult-use segment ("a"), which is created by adult-use sale legalization and thereby competes with the other two segments.

The two major changes and their resulting cost (supply) and demand shifts are described next. The magnitudes of the estimated shifts, along with elasticities and other assumptions, are reported in Chapter 7 and Chapter 8.

5.2.1 Change 1: Taxation, local regulation, and adult-use sale. In November 2016, with the passage of AUMA, cannabis was decriminalized for all adults 21 and over, including adult possession of up to one ounce, the cultivation of up to six plants for personal consumption, and the distribution of free cannabis. Also in November 2016, the sale of cannabis and possession of larger quantities of cannabis was reclassified from a felony to a misdemeanor under state law. The California cannabis market as of November/December 2017—the late 2017 situation—is understood to incorporate the effects of the legalization (but not regulation) of adult-use possession but not the effects of adult-use sale or of local and state taxation.

The first major change to this current situation results in a new hypothetical scenario (understood to be after late 2017, but not pegged to any specific date, as it is a hypothetical scenario) in which the sale of adult-use cannabis becomes legal, the state and local cultivation and excise taxes on cannabis are imposed, and the state regulations on cultivation are in place, but the retail, distribution, and testing sectors of the California

cannabis industry remain otherwise unregulated by the Bureau of Cannabis Control. Note that this is a purely counter-factual scenario, constructed for the purposes of separately isolating the impacts of proposed regulations. It does not correspond to the passage or implementation of AUMA or to any other real-life market environment that is expected to arise now or in the future. Thus the first step in our analysis is the hypothetical addition of legal adult-use sale and taxes to the current market. For the purposes of simplicity, we refer to this hypothetical situation as the “Taxation Baseline.”

The “Taxation Baseline” scenario does not correspond to the real-life partially decriminalized late 2017 situation (which does not include taxation or legal adult-use retail sales) or to the real-life regulated marketplace (in which state regulations will be in effect as well as adult-use sales). Rather, the “Taxation Baseline” hypothetical is understood to be a situation in which adult-use cannabis is legally sold at retail and all legal cannabis sales are fully taxed, and local municipalities and other state agencies have already implemented their cannabis regulations, but the Bureau’s regulations on distribution, retailing, and testing are not implemented.

Supply effects of Change 1: First, adult-use sale legalization legitimizes the industry in the eyes of trading partners and the potential labor market, and it opens up new mainstream sources of risk-averse capital, enabling investment in more efficient technology and expansion to enable scale economies. The removal of taboos and social stigma may also expand the labor market to include a new pool of potential managers and other employees. We estimate a 10% reduction in total costs (as reflected by a 10% reduction in the base price of legal cannabis) from this scenario.

Risk premium costs are also lowered in the medicinal segment as a result of adult-use sale legalization. Although their costs had not been as high as they were in the illegal market, the opening of mainstream capital labor markets that results from de-stigmatization also lowers the costs of doing business for medicinal cannabis businesses. These effects

combine to lower the total cost of supplying cannabis in the adult-use and medicinal segments, with shifts downward (right) in their respective supply curves.

Finally, cultivation and excise taxes are applied to legal cannabis at two different points along the supply chain, resulting in an additional percentage cost increase for supplying all legal cannabis, which is modeled as an additional shift upward (left) of the supply curves in the medicinal and adult-use segments.

Demand effects of Change 1: Adult-use sale legalization is expected to have four main effects on demand for cannabis. The first demand effect is the migration of some consumers from the illegal market to the adult-use market due to the lower perceived risks of punishment, unsatisfactory product quality, or fraudulent seller activity. This results in a shift outward (right) of the demand curve for adult-use cannabis and a shift inward (left) of the demand curve for illegal cannabis. Note that consumers between 18 and 20 must stay in the medicinal market if they wish to purchase legally; for more on the under-21 portion of the market, see Section 5.4.

The second demand effect is the migration of consumers from the medicinal market to the adult-use market due to adult-use retailers' competitive advantage of not requiring a medicinal recommendation, which we estimate at \$50 per year per consumer plus the inconvenience of obtaining the recommendation (plus an additional \$50 per year and an additional time commitment for consumers who want to take advantage of the sales tax break for medicinal cannabis; this requires obtaining a county identification card for which MAUCRSA permits counties to charge a fee of up to \$100, with a 50% discount for MediCal patients and a complete waiver of the fee for medically indigent patients). This results in a shift inward (left) of demand for medicinal cannabis and a shift outward (right) of demand for adult-use cannabis.

The third demand effect is the emergence of new cannabis demand from risk-averse non-medicinal consumers who had previously been unwilling to buy cannabis illegally due to

the risks of punishment, social stigma, or moral disutility. This results in a shift outward (right) of demand for adult-use cannabis.

The fourth demand effect is the expansion of the cannabis market to include tourists and other out-of-state visitors, who are prohibited from buying in the medicinal segment but can participate in a legalized adult-use market (see Section 5.2.2 for details on this effect). This results in a shift outward (right) of demand for adult-use cannabis.

5.2.2 Expected demand shift from out-of-state consumers. There are more than 260 million visits to California from residents of other places per year. These visitors spend more than \$122 billion in California.¹⁴⁷ A significant portion of this spending is on leisure goods and services. For instance, tourists have been estimated to spend \$7.2 billion per year on wine in California.¹⁴⁸ Demand for new forms of leisure spending by tourists and other visitors to California is potentially large.

Colorado, whose out-of-state visitors, like California's, contribute significantly to GDP, may be the most relevant available comparison with respect to the potential impact of an adult-use cannabis industry on tourism. A study prepared by the Marijuana Policy Group for the Colorado Department of Revenue in 2014, the first year in which Colorado's legal adult-use segment was legalized and regulated, estimated that 44% of adult-use retail cannabis sales in Denver were to out-of-state visitors (Colorado Department of Revenue, 2014). Our estimates of adult-use retail cannabis sales to out-of-state consumers in California are based in part on this Colorado figure, adjusted using some basic assumptions about the differences between the Colorado and California markets.

Given that adult-use cannabis remains illegal in most other states, California's legalized adult-use industry may attract some new visitors whose primary reason for visiting the state is cannabis tourism.

¹⁴⁷ <http://industry.visitcalifornia.com/Find-Research/California-Statistics-Trends/>

¹⁴⁸ Estimates of California wine tourism at <http://www.discovercaliforniawines.com/media-trade/statistics/>.

Some visitors to Colorado have planned trips whose primary motivation was cannabis tourism. A survey by Strategic Marketing and Research Insights (Miller, 2015), commissioned by the Colorado Tourism Office and reported in the Denver Post (Blevins, 2015), conducted 33-question surveys of approximately 3,250 tourists from Chicago, Dallas, Houston, San Diego, and several other cities, of which about 10% had vacationed in Colorado between April and September, 2015, the second year of Colorado's legal, regulated adult-use segment. 8% of the Miller (2015) respondents reported visiting an adult-use cannabis retailer, of which 85% said cannabis was a "primary motivator" of their visit to Colorado.

5.2.3 Costs of non-Bureau regulations and state and local taxation. The Taxation Baseline incorporates the effects of a variety of taxes that are imposed on both the state and local levels, as well as the effects of the state and local cultivation regulations imposed by the California Department of Food and Agriculture (CDFA)'s Cannabis Cultivation Licensing Division (CalCannabis), which include a set of regulations proposed by CalCannabis, and the effects of the state and local manufacturing regulations imposed by the California Department of Public Health (CDPH).

5.2.4 Cultivation: costs of state and local regulations and taxes. The state cultivation tax is \$148 per pound. For the CDFA regulatory compliance and tax costs, we rely on the estimate of ERA Economics, who prepared the SRIA for CalCannabis (ERA Economics, 2017). The CalCannabis SRIA estimates regulatory and tax costs separately for four different cultivation types: outdoor, indoor, mixed-light T2, and mixed-light T1.

ERA Economics (2017) estimates the total cost of local taxes and licensing fees at \$219 for outdoor, \$122 for indoor, \$134 for mixed-light T1, and \$108.50 for mixed-light T2. ERA estimates the total of all state regulatory costs, including state license fees, track and trace, labor, pesticide, labeling, and other compliance, at \$91 per pound for outdoor cultivation, \$41 per pound for indoor, \$56 per pound for T1, and \$43 per pound for T2.

Total state and local tax and regulatory costs (not including the state cultivation tax) are \$310, \$163, \$190, and \$152 for outdoor, indoor, T2, and T1 cultivators.

Assumptions about the distribution of outdoor, indoor, and mixed-light cannabis on the legalized and taxed market come with a high degree of uncertainty. ERA estimates that 60% of the state's total cannabis production by volume is outdoor, 16% is indoor, and 24% is mixed light. However, ERA also notes that outdoor cultivation is likely to make up a relatively larger portion of illegal production and a relatively smaller portion of current legal production in California.

One source of guidance on the breakdown of indoor, outdoor, and mixed-light cultivation is the numbers published weekly spot price reports from Cannabis Benchmarks. In December 2017, before taxation, indoor production made up about 40% by volume of California wholesale transactions as recorded by Cannabis Benchmarks; mixed-light made up about 25% by volume; and outdoor made up 35% by volume.

For the Taxation Baseline we must estimate shares of outdoor, indoor, and mixed-light production with the assumption of adult-use legalization, state taxation, and local taxation and regulations on cultivation (but not distribution or retailing) already in place. We expect that in this scenario, the percent of the legal market supplied by outdoor cultivators will be lower than it was in the late 2017 situation. States that have legalized adult-use cannabis tend to have cannabis markets in which a relatively lower share of product is supplied by outdoor cultivators.

Several different factors are thought to contribute to this effect. First, relatively higher local tax costs for outdoor cultivators, compared with indoor and mixed-use cultivators, tends to place outdoor cultivators in legalized and regulated cannabis states at a comparative cost disadvantage (especially in counties or municipalities where local cultivation taxes are assessed on a per-square-foot basis; this translates to three to four times higher local taxation of outdoor-grown cannabis than mixed-light cannabis).

Some other cultivation regulations (such as security requirements) are also more costly for outdoor cultivators to comply with. California is no exception to these expectations: ERA's tax and regulatory cost estimates are about 50% higher for outdoor cultivators than for indoor cultivators, suggesting that California outdoor cultivators would have competitive disadvantage. Outdoor cultivators that also ship a portion of their cannabis out of state illegally may choose not to register as legal cultivators.

The above factors, in sum, appear to have greatly impacted the market share of outdoor cannabis in other adult-use states. Cannabis Benchmarks reports the late 2017 legal market share of outdoor-grown cannabis at 10% in Oregon, 15% in Washington, and 0% in Colorado (Cannabis Benchmarks, December 22, 2017).

As noted above in "Supply Effects of Change 1," we expect adult-use legalization to help bring in more mainstream capital to the cannabis industry, which will likely result in the scaling up of existing mixed-light grow operation and the construction of new ones, reinforcing the ability of the mixed-light cultivation segment to capture more market share.

Taking into account all of the above factors, we thus assume that legal production in California in the Taxation Baseline scenario is 10% outdoor, 40% indoor, and 50% mixed-light. Because T2 mixed-light cultivation is more cost-efficient, we assumed that mixed-light cultivation would be split unevenly between T2 mixed-light cultivators (we assume 20% of mixed-light production, and thus 10% of overall production) and T1 mixed-light cultivators (we assume 80% of mixed-light production, and thus 40% of overall production).

Using ERA's regulatory and tax cost estimates for each of the four cultivation types, we thus get a weighted average of $(\$310 \times .1) + (\$163 \times .4) + (\$190 \times .1) + (\$152 \times .4) = \$178$ per pound. Based on the ratios in ERA's analysis at the cultivation level, we break this down into \$50 in state regulatory compliance and \$128 in local taxes and regulations. The

sum including the state cultivation tax is thus $\$148 + \$128 + \$50 = \326 . We use this as the AIC working assumption in the Taxation Baseline.

5.2.5 Manufacturing: Costs of state and local regulations and taxes. At the manufacturing level, we rely on the estimates in the SRIA prepared for CDPH by researchers at Humboldt State University. The Humboldt State estimate totals \$138 million in total regulatory and tax costs, including state and local taxes, state and local license fees, labeling requirements, track and trace, and other costs. At our Taxation Baseline assumption of 1.3 million pounds total legal cannabis production, this translates to \$106 per pound in manufacturing regulatory and tax costs.

Some of these manufacturing compliance costs and taxes are likely to overlap with costs already accounted for the \$324 per pound in cultivation tax and regulatory compliance costs. For instance, some businesses that both grow and manufacture may require only one round of pre-testing, labeling, and security compliance costs, rather than two separate ones, or may be subject to only one set of local or county-level fees and taxes rather than separate schedules of taxes and fees on the cultivation and manufacturing stages.

To account for this overlap, we assume a 10% lower manufacturing regulatory and tax cost, and use \$95 per pound as AIC's working estimate.

5.2.6 Total costs of state and local cultivation and manufacturing regulations and taxes. We add \$3 per pound to represent the costs of taxation of the testing segment at the cultivation level. (Although local testing taxes are technically imposed at the distribution level, not at the cultivation level, we include it in the first stage for simplicity.) Thus the total AIC working estimate of total state and local cultivation and manufacturing regulatory and tax costs under the Taxation Baseline is $(\$326 + \$95) = \$421$ per pound.

5.2.7 State excise tax. At the distribution, transportation, testing, and retail levels, taxes include a 15% excise tax on cannabis retail sales established in MAUCRSA, to be paid at

the distribution level based on an estimate of retail sales based on a determination by the California Department of Taxes and Fees Administration (CDTFA) of the “average markup” between wholesale and retail cannabis (note that at the time of the writing of this SRIA, the precise methodology for determining this markup was still uncertain, thus we simply assume 15%).

5.2.8 Local taxes and sales and use taxes on retailers, distributors, and testers. A variety of local cannabis taxes and regulations on testers, distributors, and retailers have been imposed at the county and municipal levels. Finally, we include the general state and local sales and use taxes on retail sales at the state, county, and municipal levels.

The AIC estimates of tax rates and per-pound costs are shown in Table 5.1.

5.2.9 CannaRegs estimates. Our estimates of local cannabis taxes on the segments of the industry regulated by the Bureau, as well as the local sales and use taxes, were compiled by AIC based on data provided by CannaRegs, a cannabis regulatory analysis firm that provides a web-based subscription service for those in the cannabis industry and their advisers in several US states.

CannaRegs provides access to cannabis-related rules and regulations for the states of California, Colorado, Florida, and Nevada from county, municipal and federal sources, and aggregates these rules and regulations in a database, organized into distinct categories and sorted by license type. CannaRegs continuously monitors jurisdictions for any revisions to the laws and updates their laws accordingly. The AIC analysis used CannaRegs data that were current as of late 2017.

TABLE 5.1. SUMMARY OF IMPORTANT DATA AND PARAMETERS FOR ESTABLISHING THE TAXATION BASELINE BEFORE SIMULATING THE IMPACTS OF BUREAU REGULATIONS

| VALUE | Medicinal | Adult-use | Illegal |
|--|-----------|-----------|-----------|
| INITIAL QUANTITIES (TOTAL FLOWER-EQUIVALENT LBS) | 600,000 | 700,000 | 1,300,000 |
| INITIAL RETAIL PRICES (PER FLOWER-EQUIVALENT LB) | \$3,600 | \$3,600 | \$2,340 |
| INITIAL EFFECTIVE TAX RATE | 2.5% | 2.5% | 0% |
| EXCISE TAX RATE | 15% | 15% | 0% |
| SALES TAX RATE³ | 2.1% | 8.3% | 0% |
| LOCAL TAXES AND FEES² RATE | 7.8% | 8.2% | 0% |
| LOCAL TAXES ON TESTING² RATE | 4.9% | 4.9% | 0% |
| | | | |
| STATE CULTIVATION TAXES (PER LB) | \$148 | \$148 | \$0 |
| LOCAL CULTIVATION TAXES AND REGS (PER LB) | \$128 | \$128 | \$0 |
| STATE CULTIVATION REGULATIONS (PER LB) | \$50 | \$50 | \$0 |
| MANUFACTURING TAXES & REGULATION (PER LB) | \$95 | \$95 | \$0 |
| | | | |
| DEMAND SHIFTS (QUANTITY) FROM LEGALIZATION | 0% | 30% | 0% |
| COST SHIFTS DUE TO LEGALIZATION | -10% | -10% | 10% |
| COST SHIFTS DUE TO REGULATIONS | -2% | -2% | 0% |
| WILLINGNESS TO PAY SHIFTS FROM REGULATION & TESTING | 6% | 6% | -6% |
| DEMAND SHIFTS FROM HOURS LIMITS | -2% | -2% | 1.5% |

Note: Entries for regulatory and tax relationships assume full enforcement and compliance. These calculations include summation of costs per pound and do not develop equilibrium estimates of price relationships.

¹ Unit-less elasticity parameters. ² AIC/CannaRegs estimates. ³ AIC/CannaRegs population-weighted state averages based on survey of local tax rates plus state sales and use tax; assumes that 75% of medicinal quantity is bought by patients who obtain county card and receive sales tax exemption

5.2.10 Change 2: Bureau Regulation. The second major change, which we call “Regulation,” is then applied to the Taxation Baseline, resulting in a scenario that corresponds to the actual situation expected in California upon implementation of the BCC’s proposed regulations governing cannabis sale, distribution, and testing.

Supply effects of Change 2: The costs of licensing and compliance with testing, surveillance, transportation, and other new regulations, which are calculated and explained in Chapter 6, add an increase to the cost of supplying all legal cannabis, but not to the illegal segment. This results in a shift upward (left) of the supply curve in the medicinal and adult-use segments.

Demand effects of Change 2: The contaminant and pesticide testing, labeling, and track-and-trace requirements established by the regulations communicate higher quality, consistency, and product safety to consumers, adding value to the product sold in the two regulated cannabis segments. This results in a shift outward (right) of the demand curve in the medicinal and adult-use segments.

A summary of the scenarios and supply and demand effects described above is presented in Table 5.2. Following this, we proceed to our estimates of the magnitude of cannabis quantity sold to consumers in California, a summary of published market size estimates, and finally a discussion of the under-21 and under-18 portions of the market.

Table 5.2. Summary of initial and Taxation Baseline market scenarios, changes, and supply and demand effects

| <i>Scenario</i> | <i>Supply effects</i> | <i>Demand effects</i> |
|--|---|--|
| Late 2017 Medicinal sale and possession legal Adult-use possession legal No cannabis taxes No state regulations | Starting situation | Starting situation |
| Change 1 Medicinal sale and possession legal Adult-use sale and possession legal <i>+Adult-use sale legal</i> <i>+Local cannabis taxes</i> <i>+State cannabis taxes</i> <i>+State sales taxes</i> <i>+State and local regulations on cultivation and manufacturing</i> No state regulations on retailing, distribution, or testing businesses | <p>1. Sale legalized for 21+; threat of criminal prosecution eliminated: greater efficiency and reduced operating costs translate to cost savings for legal cannabis sellers</p> <p>2. Costs decrease amongst the portion of formerly illegal sellers who switch to running legal adult-use operations</p> <p>3. Costs also decrease for medicinal sellers</p> <p>4. State and local cultivation taxes, excise taxes, and other cannabis taxes increase costs for medicinal and adult-use sellers</p> | <p>1. Migration from illegal to adult-use due to lower risk and greater convenience reduces illegal demand and increases adult-use demand</p> <p>2. Migration from medicinal to adult-use due to lack of need for medicinal recommendation reduces medicinal demand and increases adult-use demand</p> <p>3. New use from California buyers previously deterred by illegal market increases adult-use demand</p> <p>4. New use from out-of-state visitors increases adult-use demand</p> |
| Change 2 Medicinal sale and possession legal Adult-use sale and possession legal All taxes in place <i>+New state regulations</i> <i>+Taxes on costs resulting from new state regulations</i> | <p>1. Costs of compliance and the taxes on those costs increase medicinal cannabis supply costs</p> <p>2. Costs of compliance and the taxes on those costs increase adult-use cannabis supply costs</p> | 1. Higher perceived safety and quality increases demand for both medicinal and adult-use |

5.3 Quantity estimation methodology

Due to the high level of measurement error inherent to the analysis of markets that have historically been largely illegal, current estimates of the size of the California and US medicinal and adult-use cannabis markets vary widely.

The market size estimates that would be imputed by taking tax collection information or voluntary patient registration information at face value are not reliable. They vary dramatically compared with the market projections of industry analysts, informal estimates by industry insiders, and our own estimates.

We begin by explaining the methodology with which we size the market in flower equivalent pound units, and then we report our own AIC market size estimates in Table 5.2. We follow this by reporting and annotating the estimates of other researchers and industry analysts in Tables 5.3 through 5.8.

For cultivation and manufacturing estimates, we rely on projections and calculations made by the economic teams carrying out research for CDPH and DFA.

As indicated in Table 5.3, we estimate the size of the California medicinal cannabis market in late 2017 at approximately \$2.2 billion of total annual sales revenue (not including sales taxes collected) in the medicinal cannabis segment. Tax revenue is estimated by the California Board of Equalization leadership to be about \$60 million.¹⁴⁹

Based on Board of Equalization estimates and our calculations, we estimate tax revenue to be about 33% of taxes that would be owed if retailers were reporting full revenues.¹⁵⁰ That is, we used data from the AIC survey to create an index for the price of medicinal

¹⁴⁹ These data are from <https://www.boe.ca.gov/news/marijuana.htm>

¹⁵⁰ The calculation is based on estimates of how much cannabis sales revenue is generated and how much sales tax receipts are collected. <http://www.latimes.com/politics/la-pol-sac-pot-taxes-20160830-snap-story.html>

cannabis, stated as a flower-equivalent price, of \$3,600 per pound, which implies a retail quantity of flower-equivalent units of 650,000 pounds on an annual basis.

5.3.1 Flower equivalent units and THC content. An additional challenge in estimating market quantities and prices was accounting for quantities transacted within the various sub-divisions of the existing market, which, as described above, is characterized by a mix of different forms of cannabis as well as different routes from producer to end consumer. The way we confront this challenge is by stating our quantity estimates in terms of “dried flower equivalent,” which we derive as follows, benchmarking according to THC levels.

At retail, THC content is the dominant measurement used to test and communicate the strength of a portion of dried cannabis flowers or cannabis oil. THC is also the dominant means of measuring the number of portions of cannabis contained within an edible product. Converting grams of cannabis products into grams of THC is thus the only straightforward conversion between different categories of cannabis products using information provided on product labels. Measuring the grams of THC in a given end-consumer product also corresponds approximately to the amount of raw cannabis that was harvested and processed in order to generate such product.

In a sub-sample of 106 price-THC level pairs for dried flower that we solicited as part of the AIC retail price survey, we observed a mean THC level in dried flower of 23.29%, with a standard deviation of 5.46%. Median THC level was 23.30%, almost identical to the mean, suggesting that the distribution is not significantly skewed. (A more sophisticated analysis of this sub-sample is presented in Appendix Section 4.7.2.)

In our sub-sample, we observed average high prices of \$28.00 per 1/8 oz of generic dried flower with an average THC level of 19.7%, or 0.698 g THC, which is equivalent to \$40.11 per gram pure THC. For premium dried flowers the price is \$45.63 per 1/8 oz of premium dried flower with an average THC level of 24.9%, or 0.882 g THC, which is equivalent to \$51.73/g pure THC. The price increase per unit THC for premium vs. generic dried flower is \$11. 62 or 29%.

By comparison, a report on cannabis portion equivalency by Oren et al. (2015) for the Colorado Department of Revenue observes an average THC level of 17.1% THC for dried flower, and THC equivalent prices of \$55.50/g pure THC equivalent for “discounted” dried flower and \$69.40/g for “most common” dried flower, representing a price premium per unit THC of 25.0% for premium vs. generic dried flower.

Although we rely on our own sub-sample for the THC-price regression analysis presented in Section 4.7.2, we rely on the Oren et al. (2015) averages, rather than the averages from our own retail price survey, in obtaining the ratios necessary to convert between different products and estimate total volume, as the AIC survey does not include THC levels of concentrate cartridges or edibles at retailers. Due to the large variety of edible products available and the lack of standardization of such products across the marketplace, the AIC survey does not include data on retail prices of edibles.

One-eighth ounce of dried cannabis flower with 17.1% THC (the Oren et al. average) contains 0.61 grams of pure THC equivalent, whereas a 0.5 g cartridge with 62.1% THC (the Oren et al. average) contains 0.31 grams of pure THC equivalent. Using the Colorado retail prices observed in Oren et al. for conversion, THC purchased in vape-cartridge form sells for an average of 2.28 times the price of THC purchased in 1/8-oz dried flower form, and that THC in edible form sells for an average of 3.00 times the price of THC purchased in 1/8-oz dried flower form.

In the AIC survey, cartridge prices averaged \$29.20 and \$41.04 for high-end. Assuming that the THC concentration ratio for premium vs. generic cartridges is the same 1.264 (= 24.9%/19.7%) 1.264 as it is for premium vs. generic dried flowers, and taking the Oren et al. (2015) estimate of 62.1% to represent the generic market, we arrive at a generic cartridge THC price of \$97.74/g pure THC equivalent, and a premium price of \$105.91/g pure THC equivalent. This represents a generic-cartridge-to-generic-dried-flower THC-equivalent price ratio of 2.43 (= \$97.74/\$40.15), and a premium-cartridge-to-premium-dried-flower THC-equivalent price ratio of 2.05 (= \$105.91/\$51.70). The midpoint between

these two ratios is 2.24, which is close to the Orens et al. (2015) observed ratio of 2.28, which gives us confidence in the applicability of Orens et al. (2015) to the California market.

We further assume that the additional markups on THC when sold in the “high-end” forms of concentrates, cartridges, or edibles reflect the additional costs of processing cannabis into other forms, such as concentrates (which require the use of solvents or other processing agents, as well as processing machinery) or edibles (which require even more processing, starting with concentrates and then adding other food ingredients to the mix).

On the low end, meanwhile, some consumers are currently buying dried cannabis flower at prices similar to wholesale. According to anonymized AIC interviews with industry participants at the Bureau’s pre-regulatory meetings, some non-profit cooperatives with few operating expenses (none, in some cases) are operating in compliance with the Brown Guidelines (at least to an equivalent extent as retailers operating as of late 2017), and thus form part of the legal medicinal market while also displaying systematic price heterogeneity unobserved by our retail price survey. If cannabis purchased by consumers through these co-operatives were incorporated into our retail price averages, it would exert a downward pressure on the low end of the price distribution.

As these price anomalies at the high end and the low end are difficult to measure and affect only their respective tails of the price distribution, we assume that the integrity of mean and median prices estimated by our retail price survey are reasonable approximations of the market mean and median prices.

We convert the physical quantity of cannabis transacted in a given market into “flower-equivalent” pounds, wherein one flower-equivalent pound equals the THC-content equivalent of one pound marketable dried cannabis flower containing our retail price survey average of 23.30% THC. The estimates of average prices and quantities that are found throughout the SRIA and Appendix are thus stated in flower-equivalent units.

5.4 AIC quantity estimates

We estimate that as of late 2017, 25% of total cannabis by weight, in flower-equivalent units, was sold in the medicinal (legal) segment and 75% was in the illegal segment, which translates to an overall cannabis industry of approximately \$6.9 billion in late 2017. These estimates are within the range of other estimates in the industry press.

Table 5.3. AIC estimates of California cannabis market segments, late 2017

| Segment | Share by volume | Lbs flower equivalent | Retail price | Total value |
|--------------------------|-----------------|-----------------------|-----------------------|---------------|
| Legal medicinal cannabis | 25% | 650,000 | \$3,600/lb = \$225/oz | \$2.3 billion |
| Illegal cannabis | 75% | 1,950,000 | \$2,340/lb = \$146/oz | \$4.6 billion |
| Total cannabis market | 100% | 2,600,000 | \$2,655/lb = \$158/oz | \$6.9 billion |

Sources: AIC retail price survey; Board of Equalization tax data; AIC market size meta-study, taking into account credible industry, and analyst estimates as detailed in Tables 5.3a–5.8.

Note: numbers may not add exactly due to rounding.

5.5 Other quantity estimates

ArcView estimates are presented in Table 5.4a, and Table 5.4b summarizes a large variety of estimates that provide context to the size of the California market.

Table 5.4a. California cannabis market size, 2014–2016, ArcView estimates

| | Segment | | |
|---|--|------------------|---------------|
| | Legal medicinal cannabis | Illegal cannabis | Total |
| 2014 market size | \$2.69B | \$4.2B | \$6.9 billion |
| 2015 market size | \$2.76B (61% of US medicinal market, 48% of total US legal market) | \$4.5B | \$7.3 billion |
| 2016 market size | \$2.81B (56% of US medicinal market, 40% of total US legal market) | \$5.0B | \$7.8 billion |
| <i>Projected to end of year from 6-month data</i> | | | |

Source: ArcView Group annual market capsule reports, 2014, 2015, and 2016.

Table 5.4b. Industry, and analyst estimates of current California legal cannabis market size

| Market size | Relevant market | Specific mkt. projection | Publication reference | Source of value data |
|--------------------|-----------------------------|---------------------------------------|---|--|
| \$2.0 billion | California legal, medicinal | 2016 revenue from CA medicinal market | "Five More States Could Legalize Adult-use Cannabis On Election Day." Debra Borchardt, <i>Forbes</i> | David Dinenberg, CEO, KIND (cannabis software firm) |
| \$2.7 billion | California legal, medicinal | 2016 revenue from CA medicinal market | "In California, Cannabis is Smelling Like Big Business." Ian Lovett, <i>New York Times</i> | ArcView Group; New Frontier (industry analysts) |
| \$2.83 billion | California legal, medicinal | 2016 revenue from CA medicinal market | "How California's Cannabis Legalization Vote Could Impact the Entire Country". Debra Borchardt. <i>Forbes</i> | Adam Bierman, CEO, MedMen (cannabis investment firm) |

Table 5.5 summarizes a variety of estimates about the likely size of the California market in 2018 after implementation of adult-use cannabis statutes (AUMA), including an October 2016 report prepared for Truth Enterprises (University of the Pacific, 2016), which estimates total 2018 legal market quantities at 1.4 million to 1.7 million pounds.

Table 5.5. Media, industry, and analyst estimates of future size of California legal cannabis market with regulation

| Market size | Relevant market | Specific mkt. projection | Publication reference | Source of value data |
|--------------------------------------|--------------------------------------|---|--|--|
| \$4.3 billion | California legal, all segments, 2018 | 2018 total revenue from CA legal market | "How Will Cannabis Legalization Affect California's Black-Market Exports?" Madison Margolin, <i>LA Weekly</i> | New Frontier analysis (Cannabist website) |
| \$5 billion | California legal, all segments | "Future" revenue from CA medicinal and adult-use markets | "Five More States Could Legalize Adult-use Cannabis On Election Day." Debra Borchardt, <i>Forbes</i> | David Dinenberg, CEO, KIND (cannabis software firm) |
| \$6.5 billion | California legal, all segments, 2020 | Projected size of CA legal market | "Report: Legalizing cannabis in California could create \$6.5 billion market by 2020." Alicia Wallace, <i>The Cannabist</i> | ArcView Group; New Frontier |
| \$7 billion | California legal, all segments | Projected size of CA legal market | "California Treasurer Asks Trump for Guidance on Pot, Banking." Associated Press, quoted in <i>New York Times</i> . | John Chiang, California State Treasurer |
| \$8.38 billion | California legal, all segments | "Prop 64 could add \$8.38 billion in annual sales to an already robust medicinal market worth an estimated \$2.83 billion." | "How California's Cannabis Legalization Vote Could Impact The Entire Country." Debra Borchardt, <i>Forbes</i> | Adam Bierman, CEO, MedMen (cannabis investment firm) |
| \$11 billion | California legal, all segments, 2017 | "Cannabis consumables expected to grow to \$11 billion by the end of 2017." | "OutCo Announces Key Findings from New Report on Cannabis Industry In California" (Outco 2016) | OutCo (industry analyst), quoted in PR Newswire |
| 1.4 million lbs; 1.55 million lbs | California legal, all segments, 2018 | Estimates 1.4 million lbs 2018 quantity, 1.55 ("low growth")–1.69 million lbs | "Economic Impact Study of the Cannabis Sector in the Greater Sacramento Area" (University of the Pacific 2016) | Center for Business & Policy Research, University of the Pacific; prepared |

| | |
|---|----------------------------|
| ("high growth") with adult-use legalization | for Truth Enterprises Inc. |
|---|----------------------------|

Table 5.6 provides a summary of the size of the US market, and Table 5.7 looks toward adult-use legalization in more states.

Table 5.6. Media, industry, and analysts estimates of size of current US legal cannabis market

| Market size | Relevant market | Specific mkt. estimate | Publication reference | Source of value data |
|--------------------|-------------------------------|---------------------------------|---|----------------------------------|
| \$5.7 billion | US legal, all segments, 2015 | 2015 revenue in US legal market | "Report: Legalizing cannabis in California could create \$6.5 billion market by 2020" Alicia Wallace, <i>The Cannabist</i> | New Frontier (industry analyst) |
| \$6 billion | USA legal, all segments, 2016 | 2016 revenue in US legal market | "The Number of Cannabis Jobs Could Triple in the Years to Come." Sean Williams, <i>The Motley Fool</i> | Cowen & Co. (investment firm) |
| \$7 billion | USA legal, all segments, 2016 | 2016 revenue in US legal market | "Election May Be a Turning Point for Legal Cannabis". Thomas Fuller, <i>New York Times</i> | ArcView Group (industry analyst) |

Table 5.7. Media, industry, and analyst estimates of future size of US legal cannabis market

| Market size | Relevant market | Specific mkt. estimate | Publication reference | Source of value data |
|--------------------|-------------------------------|---|---|----------------------------------|
| \$22 billion | USA legal, all segments, 2020 | "Market for both adult-use and medicinal cannabis is projected to grow to \$22 billion in 4 years." | "Election May Be a Turning Point for Legal Cannabis". Thomas Fuller, <i>New York Times</i> | ArcView Group (industry analyst) |
| \$23 billion | USA legal, all segments, 2020 | 2020 revenue from US legal market | "The nation's legal cannabis industry is expected to climb to \$23 billion in 2020," | New Frontier (industry analyst) |

up from \$5.7 billion in 2015.”

| | | | | |
|--------------|----------------------------------|---|---|-------------------------------|
| \$50 billion | USA legal, all segments, by 2026 | “Investment firm Cowen & Co. believes legal cannabis sales could soar...to \$50 billion by 2026.” | “The Number of Cannabis Jobs Could Triple in the Years to Come.” Sean Williams, <i>The Motley Fool</i> | Cowen & Co. (investment firm) |
|--------------|----------------------------------|---|---|-------------------------------|

Table 5.8 provides summary statistics on the estimates from other sources in Tables 5.4a–5.7 and compares them with AIC estimates.

Table 5.8. Summary statistics from Tables 5.4a–5.7 compared with AIC estimates

Note: The calculation of means and medians for future projections group together market-size projections for different years, as well as undated market size projections, into a single statistic. Such estimates vary widely and do not appear to correlate with time scale, but in any case the summary statistics should not be interpreted as externally valid meta-statistics. We do not rely on any of the above estimates or projections for our AIC estimates or projections, but we include them in this report by way of comparison and context for our findings.

Late 2017 California legal cannabis market

Range: \$2.0 billion—\$2.83 billion
Mean: \$2.51 billion / Median: \$2.7 billion
Standard deviation: \$0.45 billion
AIC estimate: \$2.2 billion

Future California legal cannabis market with adult-use legalization and regulation

Number of estimates: 6
Range: \$4.3 billion—\$11 billion
Mean: \$7.03 billion / Median: \$6.75 billion
Standard deviation: \$2.43 billion

Current US legal cannabis market

Number of estimates: 3
Range: \$5.6 billion—\$7 billion
Mean: \$6.2 billion / Median: \$6.0 billion
Standard deviation: \$0.72 billion

Future US legal cannabis market

Number of estimates: 3
Range: \$22 billion—\$50 billion
Mean: \$31.7 billion / Median: \$23 billion
Standard deviation: \$15.9 billion

Table 5.9 summarizes a number of estimates of current and potential tax revenues from cannabis sales in California.

Table 5.9. Estimates of current and future California tax collections by mainstream, business, and industry media and analysts

| Tax Receipts | Relevant market | Specific estimate | Source of media citation | Source of value data |
|---------------|--|---|---|--|
| \$40 million | California current sales tax revenue | Current annual California state sales tax revenue collected from medicinal segment | "California regulators will be swamped by \$1 billion in pot taxes." David Downs, <i>San Francisco Chronicle</i> | Fiona Ma, Chairwoman, California BOE |
| \$777 million | California future annual tax revenue | Projected 2018 California tax revenue from all legal cannabis | "Cannabis Industry Entrepreneurs Want Donald Trump To See Them As Job Creators". Julie Weed, <i>Forbes</i> | Matt Karnes, Managing Partner, GreenWave Advisors, LLC |
| \$1 billion | California future annual tax revenue | Annual tax revenue from legal medicinal and adult-use MJ sales in California (beginning in 2018). | "California Treasurer Asks Trump for Guidance on Pot, Banking." Associated Press, quoted in <i>New York Times</i> | John Chiang, California State Treasurer |
| \$1 billion | California future annual tax revenue | "Future" annual tax revenue from legal cannabis production | "Former California Mayor Connects Cities With Cannabis Companies." Julie Weed, <i>Forbes</i> | No specific source of data given |
| billion | California future annual sales tax revenue | "Future" annual sales tax revenue from legal cannabis sales | "California regulators will be swamped by \$1 billion in pot taxes." David Downs, <i>San Francisco Chronicle</i> | Fiona Ma, Chairwoman, California BOE |

5.6 Younger consumers in the market

Under MAUCRSA, adult-use cannabis can be sold only to adults 21 or older, whereas adults between 18 and 20 are permitted to obtain a physician's recommendation for medicinal cannabis and to enter a medicinal cannabis retailer unaccompanied by a guardian. Therefore, consumers between 18 and 20 will not legally be able to substitute adult-use cannabis for medicinal cannabis (although they can illegally obtain adult-use cannabis from friends who are 21 or older, as under-21 alcohol consumers do). In terms of economic impact, this disparity in age is the single most substantive distinction between the adult-use and medicinal regulatory systems.

Cannabis sales to the 18- to 20-year-old consumer group make up a significant portion of the overall consumer cannabis market. According to Johnston et al. (2016), nearly 40% of 19- and-20-year-old Americans consume cannabis at least once per year, and this percentage grew from 2010 to 2015 (Johnston et al. 2016). In 2010, 5.1% of 19- to-20-year-old consumers surveyed reported having consumed cannabis during the prior day, 18.0% had consumed during the prior 30 days, and 30.6% had consumed during the prior year.

By 2014, those numbers had all risen sharply: 7.9% of 19-to-20-year-old consumers surveyed had consumed during the previous day (a 55% increase over the five-year period), 24.3% had consumed during the previous 30 days (a 35% increase), and 38.0% had consumed during the previous year (a 24% increase). Whether measured by frequent or infrequent consumption, Americans between the ages of 19 and 20 are more likely to be cannabis consumers than people of any other age (Johnston et al. 2016).

A 2012 California Behavioral Risk Factor Surveillance System (BRFSS) survey of 7,525 Californians observes that 9.3% of 18-to-24-year-olds—the youngest age group surveyed in the study—report being medicinal cannabis patients, the highest prevalence of any age group; 25-to-34-year-olds are in a distant second place, with a prevalence of just 5.5% (Ryan-Ibarra 2012).

Our own analysis of data from the National Survey on Drug Use and Health (NSDUH), adding in several simplifying assumptions, suggests that as of 2013, 14.4% of all cannabis consumed in the United States was consumed by people between 18 and 20, and an additional 8.1% was consumed by the 12-17 age group; in total, thus, 22.5% of total cannabis consumed in 2013 was consumed by people under 21 (NSDUH 2013).

Taking all of the above evidence into consideration, we estimate that users between 18 and 20 make up approximately 15% of the \$2 billion late-2017 medicinal retail cannabis market, or \$350 million, and 15% of the \$6 billion illegal cannabis market, or \$800 million. Whereas consumers over 21 will likely shift away from medicinal cannabis when legal adult-use cannabis becomes more convenient, some and perhaps many consumers under 21 will remain in the legal medicinal market and pay for its additional barriers to consumer entry.

A SAMHSA study of 2013 to 2014 data found a 30-day use prevalence of 8.74% amongst youths aged 12 to 17 (Hughes et al. 2015), and data from NSDUH suggested that approximately 5% of all cannabis is consumed by 12-to-17-year-olds (NSDUH 2013). Under the MAUCRSA, medicinal cannabis patients under 18 will only be able to obtain medicinal cannabis at a retailer if accompanied by primary caregivers 18-years-old or older.

Data on the whole California consumer market are summarized in Tables 5.10 and 5.11. Overall, about 14% of California residents 12 and over report cannabis use in the past year and 9% report use within the past month. The age decomposition of use is summarized in Table 5.12, which shows the peak use is in the age 18 to 24, with about 21% consuming within the prior month. Use in the age group 12 to 17 is almost 10% higher than those 25 and over.

Table 5.10. Percentage¹ of individuals aged 12 or older in California that report cannabis use in the past year, by county

| Region | Small Area | | |
|-----------------------------|-----------------------|-----------------------------|-----------------------------|
| | Estimate ² | 95% CI (Lower) ³ | 95% CI (Upper) ³ |
| Sacramento County | 15.70% | 12.99% | 18.86% |
| San Francisco County | 22.56% | 17.94% | 27.96% |
| Santa Clara County | 12.31% | 10.08% | 14.96% |
| Contra Costa County | 14.90% | 12.12% | 18.19% |
| Alameda County | 14.77% | 12.19% | 17.79% |
| San Mateo County | 13.61% | 10.69% | 17.17% |
| Los Angeles County | 13.55% | 12.40% | 14.78% |
| Orange County | 12.76% | 10.83% | 14.97% |
| Fresno County | 13.20% | 10.69% | 16.20% |
| San Diego County | 15.81% | 13.65% | 18.24% |
| San Bernardino County | 12.45% | 10.42% | 14.82% |
| California Statewide | 14.32% | 13.51% | 15.18% |

¹ Source: percentages are annual averages based on SAMHSA, Center for Behavioral Health Statistics and Quality, and National Survey on Drug Use and Health (NSDUH) 2012, 2013, and 2014.

² Source: estimates are based on a small area estimation (SAE) methodology in which sub-state-level NSDUH data are combined with county and census block group and tract-level data from California.

³ The 95% confidence (credible) intervals are based on a survey-weighted hierarchical Bayes estimation approach and are generated by Markov Chain Monte Carlo techniques.

Table 5.11. Percentage¹ of individuals aged 12 or older in California that report cannabis use in the prior month, by county

| Region | Small Area Estimate ² | 95% CI (Lower) ³ | 95% CI (Upper) ³ |
|-----------------------------|----------------------------------|-----------------------------|-----------------------------|
| Sacramento County | 10.19% | 8.04% | 12.83% |
| San Francisco County | 15.46% | 11.52% | 20.44% |
| Santa Clara County | 7.78% | 6.10% | 9.89% |
| Contra Costa County | 9.55% | 7.32% | 12.36% |
| Alameda County | 10.67% | 8.41% | 13.44% |
| San Mateo County | 9.07% | 6.72% | 12.13% |
| Los Angeles County | 8.44% | 7.55% | 9.43% |
| Orange County | 8.09% | 6.58% | 9.89% |
| Fresno County | 8.10% | 6.17% | 10.58% |
| San Diego County | 9.42% | 7.70% | 11.47% |
| San Bernardino County | 7.62% | 6.03% | 9.59% |
| California Statewide | 14.32% | 13.51% | 15.18% |

¹ Source: percentages are annual averages based on SAMHSA, Center for Behavioral Health Statistics and Quality, and National Survey on Drug Use and Health (NSDUH) 2012, 2013, and 2014.

² Source: estimates are based on a small area estimation (SAE) methodology in which sub-state-level NSDUH data are combined with county and census block group and tract-level data from California.

³ The 95% confidence (credible) intervals are based on a survey-weighted hierarchical Bayes estimation approach and are generated by Markov Chain Monte Carlo techniques.

Table 5.12 Measures of Cannabis Use in California¹, by Age Group: Estimated Numbers and Share of Age Group Population, Annual Averages Based on 2013-2014 NSDUHs

| Measure | Age | | | | |
|---|--------------------|--------------|--------------|--------------------|--------------------|
| | 12 and over | 12-17 | 18-25 | 26 and over | 18 and over |
| <i>Number of cannabis users (in thousands)</i> | | | | | |
| Past Year Use | 4,633 | 463 | 1,506 | 2,664 | 4,170 |
| Past Month Use | 2,942 | 269 | 941 | 1,733 | 2,673 |
| <i>Share of age group population</i> | | | | | |
| Past Year Use | 14.49% | 15.03% | 33.69% | 10.91% | 14.44% |
| Past Month Use | 9.20% | 8.74% | 21.05% | 7.09% | 9.25% |

Sources: SAMHSA, Center for Behavioral Health Statistics and Quality; National Survey on Drug Use and Health, 2013 and 2014.

¹ Measures are estimated using a survey-weighted hierarchical Bayes estimation approach.

6. Compliance costs of proposed regulations and alternatives

Regulations generally add to costs. The proposed regulations for cannabis add new compliance costs for medicinal cannabis businesses that are not part of their current costs of doing business without regulation (as reported in Chapter 3) nor part of the costs that are generated by the hypothetical Taxation Baseline (as explained in Chapter 5). Potential benefits of proposed regulations are discussed in Chapter 5 and Chapters 7 and 8 in terms of increased willingness to pay by consumers for additional security and safety.

This chapter will estimate three different sets of compliance costs: costs generated by the proposed regulations; costs generated by an alternative regulatory package that is less costly than the proposed regulations; and costs generated by a second alternative package that imposes higher security than the proposed regulations, but at higher costs. We present and discuss these alternative packages in Section 6.1 and Table 6.1, and the remainder of Chapter 6 estimates and compares their respective compliance costs.

In all three cases, compliance costs are applied to each of the two legal segments (medicinal and adult-use) and understood to be applied in the context of the Taxation Baseline already being in place.

Compliance costs for each segment are thus calculated as costs generated by each new scenario minus costs generated by the Taxation Baseline (taxation and adult-use legalization in place but no regulations).

Given that the Taxation Baseline is a hypothetical scenario, we used the late 2017 situation of medicinal cannabis retailers to generate our starting estimates of costs “without regulations” (generally the leftmost numerical column in the tables below).

6.1 Evaluation of compliance costs and selection of regulatory alternatives

In the following sections, we describe and estimate compliance costs under the package of proposed regulations and compare them with compliance costs under two other hypothetical packages of regulations: a lower-cost alternative package and a higher-security alternative package.

From the universe of all possible alternative regulatory packages that would meet the statutory requirements of MAUCRSA, we selected the lower-cost and higher-security alternative packages by varying particularly significant elements of the proposed regulations in terms of direct costs of compliance for cannabis businesses. We set out the chosen regulatory alternatives and axes of variation in Table 6.1.

In Sections 6.2 through 6.4, we itemize and break down the compliance costs for each of the business activities that is regulated by the Bureau. We sort costs into three groups by business function along the vertical supply chain, including distribution and transportation (Section 6.2), testing (Section 6.3), and retailing (Section 6.4). We provide a more detailed breakdowns of certain cost calculations, including video surveillance and archival costs and hours of operation restrictions.

For each of these functions, we list the compliance costs under the proposed regulations and under the hypothetical lower-cost and higher-security alternatives and compare them with the Taxation Baseline without Bureau regulations.

Finally, in Section 6.5 and Table 6.19, we summarize all of the above costs and derive total compliance costs for the proposed regulations and alternatives.

Table 6.1. Major differences between the proposed regulatory package and two alternative regulatory packages with implications for direct costs of compliance

| Impact Variable | Lower-cost alternative | Proposed regulations | Higher-security alternative |
|--|--|--|--|
| 1. Maximum batch size for mandatory testing | • No maximum batch size | • 50 lb maximum batch size | • 10 lb maximum batch size |
| 2. Retailer-to-consumer delivery restrictions | <ul style="list-style-type: none"> • No restrictions on vehicle type • No lockboxes required • No restrictions on number of employees | <ul style="list-style-type: none"> • Cars only • Lockboxes required • No restrictions on number of employees | <ul style="list-style-type: none"> • Cars only • Lockboxes required • Deliveries must be made by 2 or more employees |
| 3. Security video archival requirements | • No requirements | <ul style="list-style-type: none"> • 1280x720, 15fps • 90 days archive | <ul style="list-style-type: none"> • 1280x1024, 20fps • 90 days archive |
| 4. Cannabis waste storage and disposal requirements | • No requirements | <ul style="list-style-type: none"> • Before disposal, all cannabis waste must be: <ol style="list-style-type: none"> 1. Rendered unrecognizable and unusable 2. Disposed of by a licensed waste hauler, with documentation | <ul style="list-style-type: none"> • Before disposal, all cannabis waste must be: <ol style="list-style-type: none"> 1. Disguised by blending with solid waste or soil 2. Weighed and labeled with bill of lading with product info 3. Quarantined in a dedicated area on camera for 72 hrs |
| 5. Hours-of-operation restrictions | • None | • 6am-10pm | • 6am-10pm |

Source: AIC analysis of proposed regulations, MAUCRSA statutes, and AIC interviews with Bureau and CDPH.

6.2 Compliance costs for distribution and transportation

Table 6.2 shows our cost estimates for the distribution and transportation functions. The proposed regulations add \$45.50 per pound, whereas the lower-cost alternative adds \$48.43 per pound and the higher-security alternative adds \$51.61 per pound. See Section 6.4.3 for details on the derivation of distribution and transportation compliance costs.

Table 6.2. Itemized compliance cost estimates for distribution and transportation*All costs stated per pound flower equivalent*

| Compliance costs | Without regulations | Lower-cost alternative | Proposed regulations | Higher-security alternative |
|--|----------------------------|-------------------------------|-----------------------------|------------------------------------|
| Child-resistant packaging ¹ | - | \$42.97 | \$42.97 | \$42.97 |
| Video surveillance and archival ¹ | - | - | \$2.55 | \$3.59 |
| Waste storage and disposal ¹ | - | - | \$0.30 | \$2.44 |
| Laminated employee badges ¹ | - | - | \$0.08 | \$0.08 |
| Other compliance ² | - | \$2.53 | \$2.53 | \$2.53 |
| Total compliance costs, not including license fees | - | \$45.50 | \$48.43 | \$51.61 |
| Difference vs. unregulated situation | \$45.50 | | \$48.43 | \$51.61 |

Source: AIC estimates based on industry data.

¹ Child-resistant packaging costs calculated by comparing basic vs. compliant quantity-weighted estimates of wholesale prices for three common package sizes of dried flower. Video, disposal, and badge costs calculated based on retailer estimates. Based on 650 pounds per year per retailer. See Sections 6.4.1–6.4.3 for details.

² Includes track-and-trace. Based on 650 lbs per year retailer.

6.3 Compliance costs for testing

Some cannabis products may be contaminated with components that may harm consumers (e.g. pesticides, microbial, heavy metals, etc.), particularly to those immunologically compromised or with other medical conditions (Thompson et al., 2017; Sullivan et al., 2013). AIC estimates that testing is the category of regulations causing the largest compliance costs, with the proposed regulations adding approximately \$360 per pound to the cost of cannabis. Sections 6.3.1 and 6.3.2 present our analysis and estimates of testing costs with the proposed or alternative regulations in effect vs. testing costs in the situation without regulations.

6.3.1 Testing costs without regulations. We do not expect that the imposition of the Taxation Baseline and its associated shifts would add any extra testing costs to the late 2017 scenario that we observed empirically, so we construct our estimate for testing costs in the Taxation Baseline by analyzing data from the November 2017 AIC retail price survey and other analysis on cannabis retailers in California as of late 2017 (see Chapter 4 for

details) updated as of November/December 2017. In that survey, we observed that 6% of retail product was tested, and that most testing and labeling was only for THC and CBD content, not testing for pesticide residues or other contaminants that require wet-lab technology.

We adjust the percentage of product tested from 6% to 10%, based on our estimate that 60% of retailers who test for THC report the results in their online product descriptions. As testing was voluntary as of late 2017, with no maximum batch size, we use 50 pounds per batch.

Based on estimates from two leading testing laboratories in the state (SC Labs of Santa Cruz and Steep Hill Labs in Oakland), we estimate that the types of tests being obtained voluntarily by cannabis business as of late 2017 were priced in average at \$75 per sample. Lots were not previously customarily broken into batches of 50 pounds or less, or sampled multiple times. Only one sample per lot, however large, is generally analyzed using a sample size of 0.02 pounds. We thus obtain a net late-2017 testing cost per pound of = \$2.12 per pound, of which \$1.52 is testing cost and \$0.60 is the value of lost inventory.¹⁵¹

6.3.2 Testing regulations under MAUCRSA. In California, certain products may legally be used to control the effects of pests on cannabis crops. These are exempt from residue tolerance and registration since their active ingredients (food-grade essential oils, bacterial-based insect pathogens pesticides, or biofungicides) have been proved safe for humans (Lindsey, 2012; California Department of Pesticide Regulation, 2016). The use of other pesticides that are not registered for specific use in cannabis may result in seizure and destruction of contaminated lots. Certain common plague controls that are permitted for other crops are still illegal for cannabis, yet are commonly used (Lindsey, 2012).

¹⁵¹ We assume all testing costs to include a 25% testing lab margin (in this case, \$160 costs + \$40 margin), which is chosen based on AIC interviews with two anonymous lab operators. Note that we do not assume margins for the distribution or transportation functions: unlike testing labs, those functions were not generally previously set up as independent businesses with observable margins.

Beside pesticides, other contaminants may be present in cannabis products, such as fungi in cannabis plants that may cause opportunistic infections in patients with chemotherapy treatments, patients that have received organ transplants, and patients with AIDS.

Bacteria and fungi that invade plants after harvest are a bigger concern. For example, *Aspergillus* sp, a fungus found in cannabis samples, produce several mycotoxins, e.g., chratoxin and aflatoxins, especially under warm and humid conditions. These mycotoxins are thought to be both toxic and carcinogenic (McPartland, 2002, 2017). Heavy metals such as lead, mercury, and cadmium may also be present in cannabis plants, as they are well known as efficient soil bio-remediators.

The effects of ingesting heavy metals are cumulative, and are associated with several pathologies, including cancer (McPartland, 2017). The use of natural or syntactic fertilizers may also contaminate products and affect humans. For example, liquid fertilizers that contain nitrate can create N-nitrosamines may promote cancer (Farnsworth et al., 1976), while natural products such as bird manure and human feces have been associated with cases of pulmonary histoplasmosis, aspergillosis, hepatitis, and other diseases (Levitz, 1991; Alexander, 1987; Cates, 1975).

In 2017, a group of researchers from the University of California, Davis, warned of the possible risks of vaporized or inhaled cannabis products for immuno-compromised patients for due to pathogens may have direct access to the respiratory system (Thompson et al., 2017).

The mandatory testing of cannabis goods may benefit the industry by ensuring the quality and safety of its products. Yet inconsistencies between state and Federal drug laws, as well as few published scientific studies on the topic of cannabis contamination, still in part undermine the reconciliation of consumers' needs, security, and viability for the industry. Testing cannabis is the process of measuring desirable (cannabinoids: tetrahydrocannabinol or THC) and undesirable (pesticide, microbial, heavy metals, etc.)

elements in the plant or any derivative product (Stone, 2014; Subritzky et al., 2016; Kilmer, 2014).

While a testing framework that is too soft may fail to ensure the safety of cannabis products, one that is too strict may result in a high rate of failure with large amounts of product destroyed. This, in turn, may deter farmers to produce legally and push them to the illegal market, or may decrease the supply of cannabis for ill patients (Lindsey, 2012).

MAUCRSA provides a legal framework for the cannabis sector within California. The legislation requires that, prior distribution to retailers, cannabis goods must be tested for contaminants and/or for moisture content (pesticides residues, residual solvents and processing chemicals, microbiological impurities, heavy metals, and foreign material. See Table 6.7).

The Bureau regulations define the action levels for testing, as well as the standards for testing laboratories, including sampling procedures, validation of testing, quality assurance, and laboratory personnel qualifications. Each testing laboratory must collect records relating to the analyses executed including electronic files and video footage.

Each authorized testing laboratory must develop a plan to collect samples from all batches of cannabis, whether in dried flower, manufactured, or other form. A harvested batch corresponds to a homogeneous batch of dried flowers, trims, leaves, or any other cannabis plant matter, while a manufactured batch contains concentrate or extract from cannabis. Two samples must be collected per each batch: a primary sample and a field duplicate sample. Both samples must be tested individually.

In the proposed regulations, the maximum size of an unpacked (harvested) batch to be sampled is up to 50 pounds, and the minimum total sample size is 0.35% of the weight of the batch (but if that amount is not sufficient to complete the required tests, the sampler may collect more). For each batch, a range of number of individual samples between 7 and 9 must be applied to reach the total sample size (see Table 6.3).

Table 6.3. Minimum total sample size (0.35%) and number of samples required based on unpacked harvest batch size

| Unpacked Harvest Batch Size (pounds) | Number of Increments (per sample) |
|---|--|
| ≤ 10.0 | 8 |
| 10.1 – 20.0 | 16 |
| 20.1 – 30.0 | 23 |
| 30.1 – 40.0 | 29 |
| 40.1 – 50.0 | 34 |

Source: MAUCRSA.

With respect to manufactured cannabis products, product batch from which a primary sample and a field duplicate sample are obtained must contain no more than 150,000 units. The number of samples that must be taken depends on the number of total packaged units for retail sale in the batch (see Table 6.4).

Table 6.4. Increments required based on packed cannabis batch

| Cannabis Product Batch Size (units) | Number of Increments (per sample) |
|--|--|
| ≤ 50 | 2 |
| 51 – 150 | 3 |
| 151 – 500 | 5 |
| 501 – 1,200 | 8 |
| 1,201 – 3,200 | 13 |
| 3,201 – 10,000 | 20 |
| 10,001 – 35,000 | 32 |
| 35,001 – 150,000 | 50 |

Source: MAUCRSA.

Depending on the type of cannabis merchandise, up to nine different types of tests may be required under MAUCRSA. A cannabinoids test is required of all products. For all edible products, homogeneity is mandated, and a homogeneity test for THC must be conducted. The concentrations of six types of cannabinoids that may be present in the product—tetrahydrocannabinol (THC), tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabigerol (CBG), and cannabinol (CBN)—must be documented.

All samples must be tested for residual pesticides. A list of pesticides and maximum accepted levels in tested samples is found in Table 6.5. Samples with levels of pesticide above of the limit will fail the testing meaning that batches cannot be released to be sold. Pesticides in Table 6.5 are divided into two categories by the California's department of pesticide regulation (DPR).

Category I includes products that must not be detected, while for Category II, the DPR establishes a maximum allowable (i.e., action levels) for which laboratories must report results in unit microgram per gram ($\mu\text{g/g}$) indicating "pass" or "fail" if findings are below or above of action levels respectively. Action levels are shown in Table 6.5.

Table 6.5a. Action levels of pesticides permitted in cannabis samples (µg/g)

| Residual Pesticide | Inhalable Cannabis | Other | Residual Pesticide | Inhalable Cannabis | Other |
|--------------------------|--------------------|-------|------------------------------|--------------------|-------|
| Aldicarb (I) | 0 | 0 | Cyfluthrin (II) | 2 | 1 |
| Carbofuran (I) | 0 | 0 | Cypermethrin (II) | 1 | 1 |
| Chlordane (I) | 0 | 0 | Diazinon (II) | 0.1 | 0.2 |
| Chlorfenapyr (I) | 0 | 0 | Dimethomorph (II) | 2 | 20 |
| Chlorpyrifos (I) | 0 | 0 | Etoxazole (II) | 0.1 | 1.5 |
| Coumaphos (I) | 0 | 0 | Fenhexamid (II) | 0.1 | 10 |
| Daminozide (I) | 0 | 0 | Fenpyroximate (II) | 0.1 | 2 |
| DDVP (Dichlorvos) (I) | 0 | 0 | Flonicamid (II) | 0.1 | 2 |
| Dimethoate (I) | 0 | 0 | Fludioxonil (II) | 0.1 | 30 |
| Ethoprop(hos) (I) | 0 | 0 | Hexythiazox (II) | 0.1 | 2 |
| Etofenprox (I) | 0 | 0 | Imidacloprid (II) | 5 | 3 |
| Fenoxy carb (I) | 0 | 0 | Kresoxim-methyl (II) | 0.1 | 1 |
| Fipronil (I) | 0 | 0 | Metalaxy (II) | 2 | 15 |
| Imazalil (I) | 0 | 0 | Methomyl (II) | 1 | 0.1 |
| Methiocarb (I) | 0 | 0 | Myclobutanil (II) | 0.1 | 9 |
| Methyl parathion (I) | 0 | 0 | Naled (II) | 0.1 | 0.5 |
| Mevinphos (I) | 0 | 0 | Oxamyl (II) | 0.5 | 0.2 |
| Paclobutrazol (I) | 0 | 0 | Pentachloronitrobenzene (II) | 0.1 | 0.2 |
| Propoxur (I) | 0 | 0 | Permethrin (II) | 0.5 | 20 |
| Spiroxamine (I) | 0 | 0 | Phosmet (II) | 0.1 | 0.2 |
| Thiacloprid (I) | 0 | 0 | Piperonylbutoxide (II) | 3 | 8 |
| Abamectin (II) | 0.1 | 0.3 | Prallethrin (II) | 0.1 | 0.4 |
| Acephate (II) | 0.1 | 5 | Propiconazole (II) | 0.1 | 20 |
| Acequinocyl (II) | 0.1 | 4 | Pyrethrins (II) | 0.5 | 1 |
| Acetamiprid (II) | 0.1 | 5 | Pyridaben (II) | 0.1 | 3 |
| Azoxystrobin (II) | 0.1 | 40 | Spinetoram (II) | 0.1 | 3 |
| Bifenazate (II) | 0.1 | 5 | Spinosad (II) | 0.1 | 3 |
| Bifenthrin (II) | 3 | 0.5 | Spiromesifen (II) | 0.1 | 12 |
| Boscalid (II) | 0.1 | 10 | Spirotetramat (II) | 0.1 | 13 |
| Captan (II) | 0.7 | 5 | Tebuconazole (II) | 0.1 | 2 |
| Carbaryl (II) | 0.5 | 0.5 | Thiamethoxam (II) | 5 | 4.5 |
| Chlorantraniliprole (II) | 10 | 40 | Trifloxystrobin (II) | 0.1 | 30 |
| Clofentezine (II) | 0.1 | 0.5 | | | |

Source: MAUCRSA; DPR.

Note: The Roman numeral in parentheses after each pesticide is the category of pesticide. Category I must not be detected.

For all manufactured batches, a test on residual solvents and processing chemicals is mandatory. These solvents are used to extract cannabinoids from flowers or used during processing. All samples, in turn, must be tested and be free of *Escherichia coli* (specific Shiga toxin strain or STEC) and *Salmonella* spp. If either of these is found in a sample, the batch cannot be sold legally. Additionally, for goods that are going to be sold for inhalation (e.g. flower, kief, hashish, oil, and waxes), testing of fungal pathogens from the *Aspergillus* species (e.g. *A. fumigatus*, *A. flavus*, *A. niger* and *A. terreus*) must be done.

In addition, all samples must be tested for mycotoxins, in specific to aflatoxin B1, B2, G1 and G2, and ochratoxin A. A sample fails if it has more than 20 µg/kg of substance, making the batch fail so it cannot be released onto the market.

As of late 2017 there were no established standard methods for the chemical or microbiological testing of cannabis; however, there are procedures used in other products that have been extended to cannabis until standard methods become available in California. In this regard, all testing laboratories must follow the FDA guidelines for validation (Stone, 2015; U.S. Food & Drug Administration, 2017).

Dried flowers and solid and semi-solid edible cannabis products must be tested for water activity and moisture content. The threshold established is at or below 0.65 of partial vapor pressure of water in the sample (A_w) for dried flowers, and 0.85 A_w in case of solid and semi-solid edible cannabis products. The aim of this test is to minimize the growth of fungi and bacteria.

Table 6.5b Action levels of solvent or processing chemical permitted in cannabis samples (µg/g)

| Residual Solvent or Processing Chemical | Inhalable Cannabis | Other |
|---|--------------------|-------|
| 1,2-Dichloroethane (I) | 0 | 0 |
| Benzene (I) | 0 | 0 |
| Chloroform (I) | 0 | 0 |
| Ethylene oxide (I) | 0 | 0 |
| Methylene chloride (I) | 0 | 0 |
| Trichloroethylene (I) | 0 | 0 |
| Acetone (II) | 3100 | 5000 |
| Acetonitrile (II) | 6 | 410 |
| Butane (II) | 5000 | 5000 |
| Ethanol (II) | 5000 | 5000 |
| Ethyl acetate (II) | 5000 | 5000 |
| Ethyl ether (II) | 5000 | 5000 |
| Heptane (II) | 5000 | 5000 |
| Hexane (II) | 70 | 290 |
| Isopropyl alcohol (II) | 320 | 5000 |
| Methanol (II) | 400 | 3000 |
| Pentane (II) | 5000 | 5000 |
| Propane (II) | 5000 | 5000 |
| Toluene (II) | 30 | 890 |
| Total xylenes (ortho-, meta-, para-) (II) | 10 | 2170 |

Source: MAUCRSA.

All products must also be inspected for filth and foreign material. This item includes the examination of any material such as hair, insects, feces, packaging contaminants, and manufacturing waste and by products. If, on average, 5% or more of the sample weight is found to contain mold or foreign materials, or if an average of 1 mg or more of mammalian excreta per pound will imply a testing fail. A harvest batch that fails must be destroyed unless it can be remediated. In case of manufactured cannabis, the batch must be destroyed except in limited circumstances when remediation is appropriate.

Finally, all products must be tested for presence of four heavy metals (arsenic, cadmium, lead, and mercury). The maximum allowable action levels are based on the form of cannabis ingested (e.g. edible, suppository, sublingual, topical, transdermal, or inhalant). These maximum levels are shown in Table 6.6.

Table 6.6. Maximum allowed concentration of heavy metals ($\mu\text{g/g}$) in cannabis

| Heavy Metal | Inhalable Cannabis | Other |
|--------------------|---------------------------|--------------|
| Cadmium | 0.2 | 0.5 |
| Lead | 0.5 | 0.5 |
| Arsenic | 0.2 | 1.5 |
| Mercury | 0.1 | 3.0 |

Source: MAUCRSA.

The proposed testing regulations include DPR's current proposed set of pesticide tests as of July 2017. These proposed pesticide tests are the largest source of added costs per pound in the proposed regulations. Costs are thus expected to increase with the proposed cannabis testing regulations.

AIC analyzed the text of MAUCRSA and the proposed regulations, and interviewed several chemists, lab technicians, experts, and sales representatives at cannabis testing labs in order to construct a list of the minimum package of tests required and to determine the underlying costs. The list of tests required by the proposed regulations is shown in Table 6.7.

Table 6.7. Required laboratory tests under new regulations

| Analysis requested | Description | Products analyzed | Examples of action levels |
|---|--|--|---|
| Potency ^{*, A} | Measure concentration of the 6 main types of cannabinoids (THC, THCA, CBD, CBDA, CBG, CBN) | All | |
| Foreign material ^B | Determine presence of foreign material (hair, insects, feces, packaging contaminants, and manufacturing waste) | All | ≤ 1 insect piece, 1 rodent hair, or 1 count mammalian excreta per 3 g of product |
| Pesticide residues ^{*, 1, A, B, †} | Absence of 21 and limited presence (subject to tolerance levels set by ingestion route: Inhalable: I, or Other: O) of 45 pesticide residues | All | Chlorfenapyr (I:0, O: 0), Imazalil (I:0, O: 0), Abamectin (I:0.1, O: 0.3), Bifenazate (I:0.1, O: 5.0), etc. |
| Heavy metals ^{*, 1, C} | Limited presence (subject to tolerance levels set by ingestion route: Inhalable: I, or Other: O) ¹ of 4 heavy metals | All | Cadmium (I: 0.2, O: 0.5), Lead (I: 0.5, O: 0.5), Arsenic (I:0.2, O: 1.5), Mercury (I:0.1, O: 3.0) |
| Mycotoxins ^{*, C} | Determine presence of aflatoxin B1, B2, G1, and G2, and ochratoxin A | All | Cannot exceed 20 µg of mycotoxins/kg of substance |
| Moisture content ^A , and water activity ^C | Moisture content cannot exceed 13% per sample, and water activity (Aw) has a threshold defined according with type of product. | Flowers, solid and semi-solid products | Aw < 0.65 in dried flowers, and Aw < 0.85 for solid and semi-solid edible products. |
| Microbial impurities ^{*, A} | Screening of shiga toxin - <i>Escherichia coli</i> , <i>Salmonella</i> spp., and pathogenic <i>Aspergillus</i> species | Flowers or other inhalable products | No detection in 1 g of cannabis or cannabis product |
| Solvent and processing chemical residues ^{*, 1, A, B, †} | Absence of 6 and limited presence (subject to tolerance levels set by ingestion route: Inhalable: I, or Other: O) of 14 solvent and processing chemical residues | Processed products (edibles, oils, etc.) | 1,2-Dichloroethane (I:0, O: 0), Benzene (I:0, O: 0), Acetone (I:3,100, O: 5,000), Acetonitrile, (I:6, O: 410) |
| Homogeneity ^A | Determination of homogeneous distribution of THC within products. If first batch passes the test, it must be conducted every 6 months thereafter | Edible cannabis products | Standard deviation of THC concentration between the samples collected does not exceed +/- 10% |
| Terpenoid ^{*, C} | Determination if terpenoid profile of the sample conforms to the labeled content of terpenoids | Labeled products | Terpenoids cannot exceed the labeled content of total terpenoids, +/- 10% |

* The licensed laboratory must maintain ISO/IEC 17025 accreditation to conduct these analyses.

¹ Results of residuals and contaminants must be reported in unit micrograms per gram (µg/g) of cannabis.

† Testing category I of pesticides and Category II of solvents and processing chemicals must be conducted in cannabis harvested or manufactured on or after January 1st 2018, and testing category II of pesticides and Category I of solvents and processing chemicals must be conducted in cannabis harvested or manufactured on or after July 31, 2018.

A: All cannabis harvested or manufactured on or after January 1, 2018, must pass testing for this item.

B: All cannabis harvested or manufactured on or after July 31, 2018, must pass testing for this item.

C: All cannabis harvested or manufactured on or after December 31, 2018, must pass testing for this item.

6.3.3 Testing costs under the proposed regulations. Testing for only THC and CBD concentration, as was typically done in the industry as of late 2017, is relatively quick and inexpensive, and can be done with portable technology because it uses light-based techniques. (However, there are reports of widely variable and inaccurate testing results.) Testing for pesticides and other compounds requires wet-lab procedures that are relatively immobile and require the use of costly chemical reagents and the employment of skilled lab technicians with master's-degree-level educations.

The cost of each test will depend on the type of good produced, due to differences in the types and costs of the analyses required. For example, flowers and trim do not need tests for homogeneity or residuals of processed chemicals, thus substantially lowering their testing costs vs. the price of testing edibles, tinctures, or suppositories, which require additional tests.

6.3.4 Incumbent cannabis testing facilities and their prices. One important angle on assessing testing costs was to survey testing labs in California that were already offering or preparing to offer MAUCRSA-compliant testing services. Using Google and the directory of the Association of Commercial Cannabis Laboratories (ACCL), we located 16 different firms and 22 facilities of testing laboratories that were operating in California as of late 2017. In November and December 2017, AIC conducted a survey of their prices. We made requests by email or phone, asking for descriptions of the types of analyses offered if they were not advertised in their websites. We asked for their retail and wholesale prices, and for their sampling costs, if offered as a separate service.

Most of the testing lab facilities are located in the Bay Area and certain parts of Southern California. As of late 2017, only two firms offered all set of analyses required by MAUCRSA (29% offer water activity tests, 95% cannabinoids, 14% filth foreign material, 33% heavy metals, 10% homogeneity, 95% microbial, 29% mycotoxins, 90% pesticide residuals, and 95% solvent residuals analysis), and only one was prepared to offer information on sampling costs.

The locations of the 22 testing facilities are indicated as red dots in the map in Figure 6.1.

Figure 6.1. Testing lab facilities currently located in California

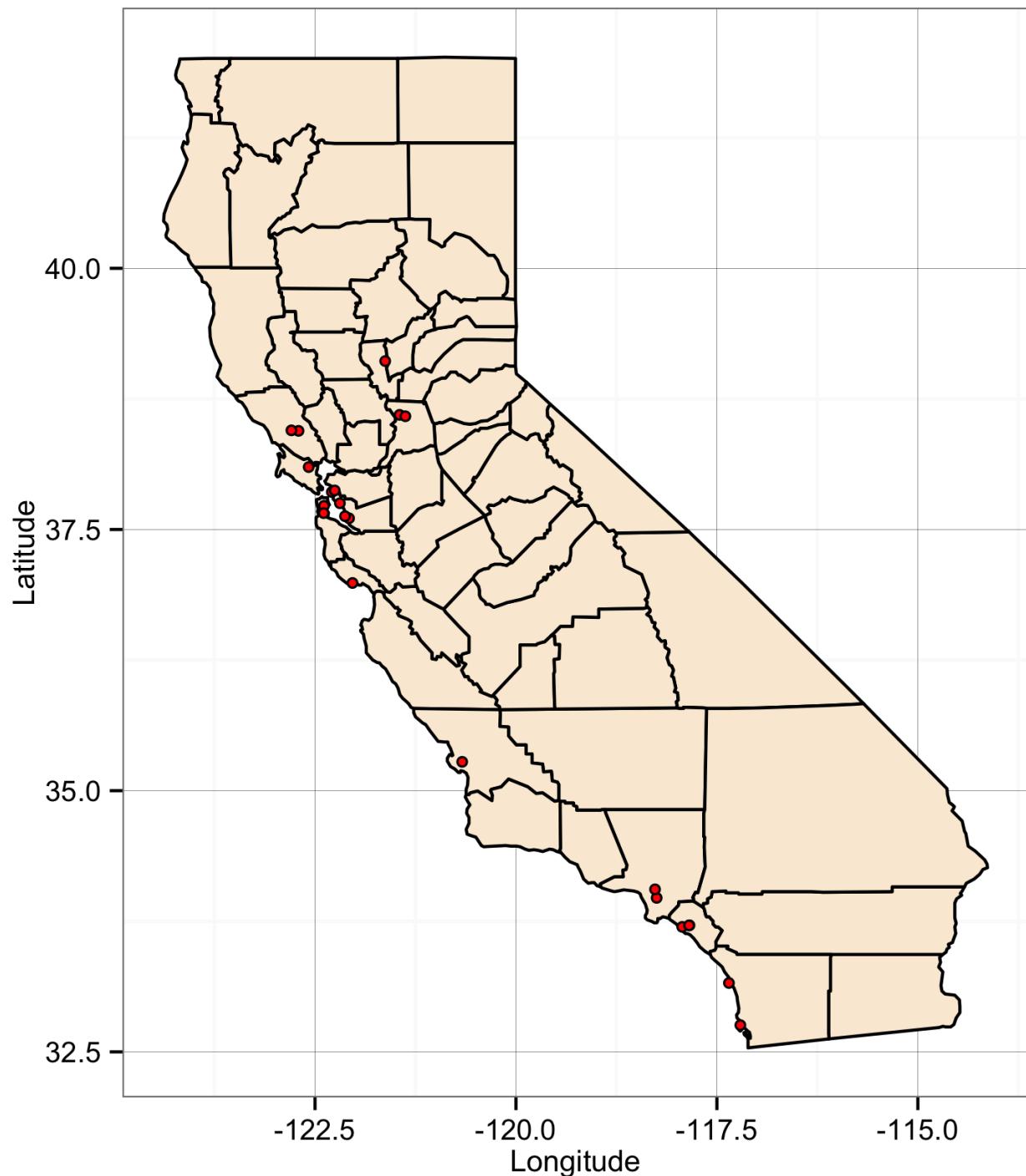


Table 6.8 summarizes retail prices from testing laboratories that provided information upon request or are advertised in their websites.

Table 6.8. Retail prices of analyses and testing sets per sample, USD

| Type and costs of required analyses | Avg | Min | Max | Std. Dev. | N |
|---|------------|------------|------------|------------------|----------|
| 1. Water activity and moisture content | \$30 | \$10 | \$65 | 23 | 5 |
| 2. Cannabinoids | \$78 | \$60 | \$100 | 12 | 7 |
| 3. Filth and foreign material | \$25 | \$15 | \$40 | 13 | 3 |
| 4. Heavy metals | \$157 | \$75 | \$260 | 75 | 5 |
| 5. Homogeneity test | \$433 | \$300 | \$500 | 115 | 3 |
| 6. Microbiological impurities | \$89 | \$60 | \$150 | 31 | 7 |
| 7. Mycotoxins | \$80 | \$50 | \$150 | 41 | 5 |
| 8. Residual pesticides | \$141 | \$80 | \$250 | 70 | 7 |
| 9. Residual solvents and processing chemicals | \$99 | \$70 | \$150 | 27 | 7 |

| Cannabis types & costs of required testing set | Avg | Min | Max | Analyses required |
|---|------------|------------|------------|------------------------------|
| Flowers and trim | \$600 | \$350 | \$1,015 | 1, 2, 3, 4, 6, 7, 8 |
| Concentrates: kief and hash | \$570 | \$340 | \$ 950 | 2, 3, 4, 6, 7, 8 |
| Concentrates (others) | \$669 | \$410 | \$1,100 | 2, 3, 4, 6, 7, 8, 9 |
| Topical and transdermal | \$669 | \$410 | \$1,100 | 2, 3, 4, 6, 7, 8, 9 |
| Edibles, tinctures and suppositories | \$1,132 | \$720 | \$1,665 | 1, 2, 3, 4, 5, 6, 7, 8, 9 |

Source: Testing laboratory price lists; AIC interviews with testing laboratories in California.

Note: Values correspond to retail prices. Bulk pricing might decrease up to 30% subject to the number of samples (e.g. 100 or more) tested or volume in monthly sales (e.g. \$20,000 volume in sales monthly).

6.3.4. Overview of testing cost calculations. We estimated the cost of testing based on cost of sampling (i.e., field section) and cost of test of dried flowers (i.e., the set of analyses required in laboratory section). We assumed that the industry would tend to analyze raw materials before processing them, to diminish losses due to possible test rejections, and losses due to sampling and failing tests. We also assumed that any initial supply shortage of certified testing labs would be resolved as more testing labs enter the market and become certified, so we did not account for early profit-taking by testers if demand exceeds supply.

The proposed regulations also add certain restrictions on the collection, storage, labeling, and disposal of samples that are relatively minor compared with the cost of pesticide testing. We estimated these costs as well (including gloves, masks, boots and specialized sampling equipment), which we call “handling costs.”

These handling costs are separate from the compliance costs for the track-and-trace requirements mandated by the MAUCRSA statutes, which are included as costs in all three regulatory scenarios as part of “other compliance costs.” In the lower-cost alternative, we also leave out the restrictions regarding collection, storage, labeling, and disposal of samples that are not part of the MAUCRSA statutory requirements. In the higher-security alternative, we left the restrictions in place.

We also calculated the lost value of the amount sampled, which is a relatively minor cost. We did not vary this in the lower-cost or higher-security alternatives.

The proposed regulations also establish a 50-pound maximum batch size for testing. Batch-size regulations may allow for more-precise testing and are tied to homogeneity of a batch to assure that the sample reflects the characteristics of the batch.

Maximum-batch-size regulations add costs to testing, as they require distributors to divide up larger cannabis lots into multiple batches for testing, thus increasing the average cost per pound of testing. For example, while a 50-pound maximum batch size rule would not affect the price per pound of testing a five-pound lot, it would double the price per pound of testing a 100-pound lot.

There is no statutory guidance from the MAUCRSA on maximum batch sizes, so a less costly alternative would be to specify no maximum batch size for testing. We thus assume no maximum batch size in the lower-cost alternative package of regulations. In the higher-security alternative scenario, we assume 10 pounds as the maximum batch size (as in Washington State), but otherwise assumes the same set of pesticide residue minimums, handling requirements, etc.

One item that is expected to have a substantial impact on the cost of testing is losses associated with failing tests due to detection of several contaminants above limits (pesticide residues, heavy metals, etc.). A particular concern is the high prevalence of pesticides use in California. A recent investigation found that 93% of 44 samples from 15 retailers in California found pesticide residues (Grover et al., 2017). While there has not been systematic evidence about the percentage of likely rejections, we expect relatively high rates of failure that impose significant costs during the first year of fully implemented regulations. For example, 60% of the cases investigated between 2015 and 2017 by the Department of Agriculture in Colorado found positive pesticide residues detections at or above the lab's method detection level for the pesticide active ingredient in question. (Colorado Department of Agriculture, 2018).

However, we anticipate a decreasing trend in the long run because of adjustments of growing techniques and use of allowed active ingredients (e.g. azadirachtin, Beauveria bassiana, etc.; DPR, 2016), in addition to the possibility of pre-testing (which would itself add costs which we do not account for here), as well as the self-selection of pesticide users who choose to move to the illegal market.

The cost per pound of cannabis testing, as required by the proposed regulations, can be broken down into three parts: (1) the laboratory cost, comprised by the testing cost per sample and costs of video, waste storage and disposal, track-and-trace, and badges required by the regulatory package weighted for small, medium and large-scale testing laboratories, plus the sampling cost; (2) the value of lost inventory due to sampling and proportion destroyed due test rejections; and (3) the remediation costs for lots that are rejected during the first test.

First, the cost of testing per sample is estimated using the annual number of samples tested (q) in function of capital investment (k), annual maintenance (m), labor (l) and other consumables (x) used during processing and analyses. Our estimates are based on testing required for dried cannabis flowers, as we anticipate that the industry will prefer to analyze raw materials to reduce the risk of losses due to possible test-rejections. Also,

we expect that any initial supply shortage of testers would be resolved as more testers enter the market, so we did not account for early profit-taking by testers if demand exceeds supply.

We used estimated averages small, medium, and large-scale testing labs ($i=1, 2, 3$). We assumed that businesses in each scale category conduct the maximum number of annual tests (q) given the use of alternative combinations of k , m , l , and x , as expressed by equation 1:

$$q_i = f(k_i, m_i, l_i, x_i) \quad (1)$$

A necessary condition is that laboratories operate at their efficiency frontier, where the total annual cost (c) of testing is expressed by equation 2:

$$c_i(q_i) = vk_i + am_i + wl_i + zx_i \quad (2)$$

The parameter v indicates costs of investing in a specific number of testing instruments (see Table 6.9) as well as start-up equipment required. The parameter a represents the maintenance and other annual costs that support capital, while w denotes wages and z the costs of direct and indirect consumables used during testing. These parameters affect laboratory testing decisions, and by extension, the number of samples tested per year.

Information regarding fixed and variable costs was gathered from meetings, phone calls, and email exchanges with testing cannabis laboratories from California, large equipment supplier companies (e.g., Agilent Technologies Inc., Schimadzu Scientific Instruments Inc., and VWR), and researchers who advise the cannabis-testing industry.

6.3.5. Calculation of capital costs. Capital costs include the cost of instruments ($j=1, 2\dots$) used to conduct specific analyses (e.g. High-performance liquid chromatography or HPLC used to test cannabis potency), as well as instruments and materials needed to start-up a testing laboratory, including those required for sampling procedures (e.g., balances,

microscopes, centrifuges, etc.). The instruments necessary for the required tests are shown in Table 6.9.

Table 6.9. Types and number of instruments for different analyses required and estimated running time per sample

| Instrument | Type of analysis | No. Instruments ¹ | Running time (min) |
|---|------------------------------------|------------------------------|--------------------|
| High-performance liquid chromatography (HPLC) | Cannabinoids | S=1, M=1, L=2 | 10 |
| Inductively coupled plasma mass spectrometry (ICP-MS) | Heavy metals | S=1, M=1, L=2 | 5 |
| Liquid chromatography-mass spectrometry (LCMS) | Residual pesticides and mycotoxins | S=1, M=2, L=3 | 12 |
| Gas chromatography-mass spectrometry (GCMS) | Residual pesticides and solvents | S=1, M=2, L=4 | 20 |
| Real-time polymerase chain reaction test (PCR) | Microbial | S=1, M=1, L=2 | 4 |
| Moisture balance (MB) | Moisture | S=1, M=1, L=2 | 10 |

¹ Number of instruments of each type assumed to be used by small (S), medium (M), and large-scale (L) labs

We also incorporate costs associated with protocols necessary for installation, and operational standards that must be met and certifications that must be obtained once the instruments are installed in the laboratory. We convert these costs into an annual payment plan (p) using a 7.5% discount rate (r) and a 10-year horizon (n), as follows:

$$p = \frac{r \sum_{j=1}^n v_j k_j}{1 - (1 + r)^{-n}} \quad (3)$$

Small-scale labs are assumed to operate with minimum capital investment (i.e., one instrument of each type), and their testing capacity is constrained by the running times of equipment. Medium-scale laboratories are expected to have some operational redundancy (i.e., more than one instrument of the same type) for less efficient instruments. Large-scale laboratories are expected to have operational redundancy for all equipment (Table 6.9 shows the number of instruments used by each type of lab). However, operational redundancy does not imply that running capacity doubles. Indeed,

laboratories usually do not fill up 100% of their equipment capabilities to leave a margin (i.e., unused volume) when instruments break down.

We use costs of acquisition and maintenance of ISO/IEC-17025 accreditation for conducting specific tests, and annual maintenance plans to prevent or address ongoing issues of instruments. In addition, we include annualized rent facilities, basic utilities, license fees, and 30% sales, general and administrative costs from annualized costs.

6.3.6. Calculation of labor costs. We include labor for specific tasks required by the proposed regulations, from sampling to delivering results adjusting annual wages according to the minimum qualifications specified by MAUCRSA. We assume that:

- (1) Samplers must be trained to sample cannabis, and must have either at least two years of college education or a high school diploma plus one year of full-time practical experience in a related field.
- (2) Level 1 laboratory technicians receiving and processing samples to conduct analysis must have at least two years of college education, with coursework in a related field.
- (3) Level 2 laboratory technicians must hold a master's degree in a related field, or a bachelor's degree plus 3 years of experience in a related field.
- (4) Lab managers, supervisors, and directors must have a doctoral degree, or a master's degree plus 2 years of experience in a related field, or a bachelor's degree plus 4 years of experience in a related field.

See Table 6.10 for a summary of AIC estimates of basic staffing needs for an MAUCRSA-compliant testing lab.

Table 6.10. Estimated staffing costs for a basic cannabis testing laboratory

| Position | Description | Assumed processing capacity per 8-hour workday | Annual salary per employee |
|------------------------|--|--|----------------------------|
| Director | Quality check, result validation | 100 | \$200,000 |
| Lab Manager | Run analyses, read and interpret results | 50 | \$150,000 |
| Lab Technician Level 2 | Extraction, subsampling for each individual test, preparing testing sample | 50 | \$90,000 |
| Lab Technician Level 1 | Sample reception, homogenization of the sample, weighting, extraction | 50 | \$60,000 |
| Sampler | Sampling extraction, weighting, inspection | 50 | \$50,000 |
| Office Staff | Reception, client relations | | \$50,000 |

6.3.7. Calculation of operating costs. We collected cost information of consumables needed to run testing instruments (e.g., solvents as Formic Acid in Acetonitrile used by HPLC equipment) and of flow rates per instruments to estimate specific operational costs for each type of analysis. In addition, we include materials and disposables that are used during processing samples and analyses, such as glassware and plastic ware, e.g., tubes, cuvettes, flasks, funnels, etc. and disposables used by personnel such as masks, gloves, booties, etc.

6.3.8. Calculation of general compliance costs. We include proportional costs of video, waste storage and disposal, track-and-trace, and badges based on retailer estimates, assuming that medium and small-scale laboratories operate with a respective 25% and 50% of lower efficiency than large laboratories.

Testing cost per sample is calculated by dividing total annual cost (i.e., capital, labor and other costs) by the effective number of samples tested per year in each testing laboratory (e.g., small, medium or large-scale laboratory). As mentioned above, the annual number of samples tested depends on k, m, l, and x; but also it depends on the running capacity, testing efficiency, and the total number of operating hours at each lab.

Running capacity varies between different laboratory scales. We assumed that small, medium and large-scale labs leave a 45%, 30% and 20% of total running capacity as a non-operational¹⁵² time for their equipment. Additionally, we penalized the total annual number of samples tested subject to the testing efficiency.¹⁵³

We assumed 80%, 85% and 95% testing and processing efficiency for small, medium, and large-scale labs, respectively. Finally, we set 8, 8, and 14 working hours per day, respectively, over 250, 260, and 290 days in a year, respectively, to estimate the total operating hours per year of small, medium, and large-scale labs.

We used 15% as a risk premium (which could alternatively be viewed as an operating margin) over the total cost (c) to estimate total revenues and define the cost of test per sample (c^T) (equation 4):

$$c_i^T = \frac{0.15 * c_i(q_i) + c_i(q_i)}{q_i} \quad (4)$$

6.3.9. Calculation of sampling costs. We assume a 1:10 ratio of testing laboratories to cannabis distributors in California.¹⁵⁴ To estimate sampling costs, we calculated transportation and labor costs using the distance (in miles) between labs and distributors, as well as time spent traveling and sampling batches and the cost of materials used to sample.

We assumed that laboratories are able to collect at least 20 samples in one round of sampling and that daily sampling is not necessary. We used 15 minutes as the average time used to retrieve one sample from a batch, and we estimated that 1.6 hours would be spent on each sampling visit. We set \$50 as a cost of materials per visit that includes

¹⁵² This time is devoted to maintenance or to any other time spent to solve operational issues or malfunction.

¹⁵³ The number of samples that do not need to be retested out of the total number of tested samples. Usually, a proportion of samples need to be retested due to discrepancies of results. This could occur for multiple reasons, e.g., borderline results, inexperienced labor, failure of equipment, etc.

¹⁵⁴ For this analysis, we assume 2000 retailers, 200 distributors and 20 testing labs in California.

disposables like gloves, masks, booties, etc. Finally, following the Federal reimbursement rate of California, we used \$0.535 as the operating cost per mile. The total cost (material, labor, and transportation costs) is divided to the total number of samples collected in a round to estimate the sampling cost (c^S).

We use four scenarios where we include the weighted laboratory costs,¹⁵⁵ including analysis of primary samples, field duplicates, and sampling (i.e., $\bar{c}^L = 2\bar{c}^T + \bar{c}^S$) to estimate a per-pound lab cost (i.e., $\theta = \frac{\bar{c}^L}{lb}$).

For testing costs in the “Taxation Baseline” scenario, we assume that fall 2017 levels of voluntary testing for marketing and internal quality control (i.e., only a relatively small amount of potency testing) are in place, but costs of the full testing regulatory package have not been imposed. For this scenario, we assume a \$75 as testing (c^T) and \$1 as sampling cost (c^S) per sample, assuming 10 grams sampled per batch.

To estimate the additional costs of the proposed package of testing regulations, we assumed that 25% of total batches are about 8 pounds, 25% are about 20 pounds, and 50% are about 50 pounds, so we use a weighted lot size in the California wholesale market of 32 pounds. Third, we evaluated two additional alternatives: a lower-cost alternative that relaxes to no limits the batch size to be tested; and a higher-cost alternative that limits the batch size up to 10 pounds.

We define “Lab costs per pound passing and marketed” ($\hat{\theta}$) to include pre-testing, rejection rates and remediation (discussed in sections 4 and 5), and it is defined the following equation:

$$\hat{\theta} = \theta\eta \quad (5)$$

¹⁵⁵ The weight is based on the market share that 20 testing labs distributed into small, medium and large-scale are able to supply based on total Cannabis tested for the legal market.

In equation (5), η represents the number of pounds that need to be tested per pound marketed. The symbol η is defined as $\eta = \frac{\alpha}{\beta}$, where α represents the total pounds need to be tested per pound marketed, while β the amount that passes the test per each pound tested.

6.3.10. Calculation of total per-pound laboratory costs. The lab cost per pound without regulations is \$1.52. The weighted average is constructed using a 6%, 33%, and 61% of market share distribution for small, medium, and large-scale labs, following their respective testing capacities and a testing demand of 1.9 million pounds of Cannabis.¹⁵⁶

The estimated weighted lab cost per pound under the regulatory package is \$38, but lab costs per pound passing and marketed increased up to \$57 due to a total of 1.51 pounds must be tested per pound sold in the legal Cannabis market (Table 2). We estimate that the lab costs per pound passing and marketed for the proposed regulations is approximately \$38, vs. \$23 for the lower-cost alternative regulations and \$215 for the higher-security alternative regulations.

6.3.11. Calculation of lost inventory costs. For the Taxation Baseline scenario, we assume that 10 g is sampled, using a 50-pound maximum batch size for testing. We assume that the wholesale price of cannabis flowers is equivalent to \$1,360 per pound. Thus the lost inventory cost per pound is \$0.60.

For the remaining 3 scenarios (*proposed testing regulatory package, lower-cost alternative, and higher-cost alternative*), we estimated the value of lost inventory, including two components: (1) the value of cannabis sampled and re-sampled for testing, and (2) the value of inventory lost due to a failed test. We assumed that the wholesale price of Cannabis flowers is equivalent to \$1,360 per pound.

¹⁵⁶ This estimate is obtained by multiplying the estimated amount of Cannabis produced in California and subject to be tested times 1.51, which is the amount of Cannabis tested per one pound passing and marketed (See details in Section 4).

The per-pound value of Cannabis sampled/re-sampled (ω) is calculated based on 0.7% of batch size sampled for testing, which includes primary samples and field duplicates, the remediated proportion ($\mu=0.08$) and 25% as the assumed proportion of Cannabis that is pre-tested (τ) (equation 6):

$$\omega = \$9.52(1 + \mu + \tau) = \$12.66 \quad (6)$$

We assume that 16% of samples failed the first test. (Initial failure rates are reported to be much higher than this, but we assume compliant adjustment over time on the part of cannabis businesses). Among failed samples, we assume that businesses will attempt remediation on half of them ($\mu=0.08$), and that 50% of those will pass in the second (remediation) testing phase. We therefore assume a net failure rate (including remediation) of $8\% + (8\% \times 50\%) = 12\%$ failure rate as of one year after implementation of the proposed regulations. The total per-pound value of inventory destroyed due to failed testing is equivalent to \$163.20 (\$1,360 x 12%).

Consequently, lost inventory costs per pound tested are \$175.86 (\$12.66+\$163.20), which translates to \$199.84 per pound passing the test (i.e., assuming that a total of 0.88 pounds are marketed per 1 pound tested). See Table 6.11 for a summary of these costs.

6.3.12. Calculation of remediation costs. We estimated the total pounds submitted for attempted remediation as a function of the rejection rate at the first round of testing (16%) and the proportion of batches that are successfully remediated (50%). The resulting per-pound cost of remediation is \$1.60 per pound tested, or \$1.82 per pound passing testing and marketed (again assuming that a total of 0.88 pounds are marketed per 1 pound tested).

Summary results for the itemized costs of testing are shown in Table 6.11.

Table 6.11. Itemized testing compliance costs*All costs stated per pound flower equivalent, except where noted*

| Compliance cost item | <i>Lower-cost alternative</i> | <i>Proposed regulations</i> | <i>Higher-security alternative</i> |
|---|-------------------------------|-----------------------------|------------------------------------|
| Max batch size to be tested | None | 50 | 10 |
| Lab costs | | | |
| Per-pound lab costs | \$23.34 | \$37.92 | \$142.18 |
| Lab costs per lb passing and marketed | \$35.28 | \$57.31 | \$214.88 |
| Lost inventory costs | | | |
| Total lbs lost due to samples submitted for testing plus failed and destroyed product | 180,408 | 180,408 | 180,408 |
| Per-pound value of cannabis sampled | \$12.66 | \$12.66 | \$12.66 |
| Per-pound inventory loss due to failed tests | \$163.20 | \$163.20 | \$163.20 |
| Cost of lost inventory, per lb passing | \$199.84 | \$199.84 | \$199.84 |
| Remediation costs | | | |
| Per-pound cost of remediation | \$1.60 | \$1.60 | \$1.60 |
| Cost of remediation per lb passing | \$1.82 | \$1.82 | \$1.82 |
| Total cost per lb passing testing | \$236.94 | \$258.97 | \$416.54 |
| Cost per lb without regulations | \$2.12 | \$2.12 | \$2.12 |
| Per lb difference vs. Taxation Baseline | \$234.82 | \$256.85 | \$414.42 |

Note: Assumes that the costs of logistics, materials, and procedures within the lab, labor hand, and margin are internalized within test price.

6.4 Compliance costs for retailing

The proposed regulations have a multi-faceted impact on the cost of selling cannabis at retail. Table 6.12 details and summarizes total compliance costs for retailing, not including retail delivery.

Table 6.12 Itemized compliance cost estimates for retailing, not including delivery, hours-of-operation restrictions, or license fees

All costs stated per pound flower equivalent

| Compliance costs | Taxation Baseline⁶ | Lower-cost alternative | Proposed regulations | Higher-security alternative |
|---|--------------------------------------|-------------------------------|-----------------------------|------------------------------------|
| Video surveillance and archival ¹ | - | - | \$19.97 | \$35.90 |
| Waste storage and disposal ² | - | - | \$3.07 | \$24.43 |
| Laminated employee badges ³ | - | - | \$0.76 | \$0.76 |
| Other compliance ⁵ | - | \$25.31 | \$25.31 | \$25.31 |
| Total retailing compliance costs per lb, not including delivery, hours-of-operation restrictions, or license fees | - | \$25.31 | \$49.11 | \$86.40 |
| Per lb difference vs. Taxation Baseline | | \$25.31 | \$49.11 | \$86.40 |

Source: AIC calculations based on industry data.

¹ For assumptions, explanations, and cost detail for video surveillance, see Table 6.13.

² Assumes \$2,000 per year cost, 650 lbs/yr/retailer.

³ Assumes \$53/employee/year, 9.4 employees/retailer, 650 lbs/yr/retailer.

⁴ Assumes \$0.67/package, ¼ oz average purchase.

⁵ Includes packaging and track-and-trace compliance. Assumes \$1,060/yr/employee, 9.4 employees/retailer, 650 lbs/yr/retailer, plus AIC estimate of \$10 per pound for track-and-trace compliance.

⁶ Taxation and adult-use sale legalization baseline without regulations applied.

6.4.1 Surveillance and video archival compliance costs. The proposed regulations require license holders to maintain security cameras with 1280 x 720 resolution at 15 frames per second, and to maintain a 90-day video archive of footage from these cameras. We estimate that the average retailer will require five or six cameras to achieve compliant coverage. Detailed calculations are shown in Table 6.13.

Table 6.13. Itemized compliance cost estimates for retailer video surveillance and archiving

| Compliance variables and costs | Taxation Baseline⁴ | Lower-cost alternative | Proposed regulations | Higher-security alternative |
|--|--------------------------------------|-------------------------------|-----------------------------|------------------------------------|
| Number of cameras | - | - | 6 | 6 |
| Resolution | - | - | 1280x720 | 1280x1024 |
| Frames per second | - | - | 15 fps | 20 fps |
| Days of storage | - | - | 90 | 90 |
| Amount of storage required ¹ | - | - | 28.5 TB | 54 TB |
| Storage cost per month ² | - | - | \$962.00 | \$1,825.00 |
| Equip, maintenance & power cost per month ³ | - | - | \$120.00 | \$120.00 |
| Total cost per month | - | - | \$1,945.00 | \$1,945.00 |
| Total cost per year | - | - | \$12,984.00 | \$23,340.00 |
| Total cost per lb ⁵ | - | - | \$19.97 | \$35.90 |
| Per lb difference vs. unregulated situation | | - | \$19.97 | \$35.90 |

Source: AIC estimates based on industry data.

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¹ TB = terabytes. Surveillance video storage requirement estimates from Seagate.com.

² Based on Amazon Cloud storage price quote of \$0.033/GB.

³ Assumes \$20/camera/month equipment, software, maintenance, and power costs.

⁴ Taxation and adult-use sale legalization baseline without regulations applied.

⁵ Based on 650 lbs/retailer on average.

Because MAUCRSA does not state any security video or archival rules and there is no current mandatory cost of video surveillance archival in the unregulated state, the Taxation Baseline, and the lower-cost alternative for mandatory security video costs are both set to zero. Under the proposed regulations, we estimate the cost per pound of retail medicinal cannabis to rise by about \$36 per pound compared with the lower-cost alternative.

We tighten this requirement in the higher-security alternative to 1280x1024 at 20 fps with a 90-day archive, providing a level of security that is in keeping with the highest security archival requirements in other industries. The 90-day video archival requirement achieves

Bureau regulatory enforcement and non-Bureau-related law enforcement objectives which have benefits to the public safety discussed above.

Other additions to retailer costs are labeling and track-and-trace requirements, for which the proposed regulations are not substantially more costly than what would be required by the lower-cost alternative, as MAUCRSA requires a track-and-trace system. For all functions, these costs are included in the “other compliance” category in all scenarios with regulations, including the lower-cost alternative, and thus do not impact the differences between the costs of proposed regulations and the costs of lower-cost or higher-cost alternatives.

6.4.2 Waste storage, disposal, and badge compliance costs. The proposed regulations specify that licensees must follow certain procedures in order to dispose of cannabis waste. Licensees must render cannabis waste “unusable and unrecognizable” before disposing of it. They may either compost the waste themselves, in compliance with Title 14 of the California Code of Regulations, Chapter 3.1, Sections 17850 *et seq.*, which requires following a number of composting and waste-mixing rules, including an annual inspection of the composting facility by an enforcement agency; or, alternatively, they may contract with a licensed waste hauler for removal, which must provide a certified weight ticket and other basic documentation. We assume that it is unlikely that retailers will have the type of premises that would be suitable to meet these composting requirements, and that retailers will typically contract with waste haulers for removal.

Cannabis waste must be stored in a “secured waste receptacle or in a secured area on the licensed premises,” meaning that physical access to the receptacle or area is restricted to the licensee and its employees, agents, and contractors, including waste haulers. For a retailer, we assume that a lockbox, and not a separate room, will suffice to store waste that is periodically removed by the waste hauler.

We estimate that the cost of equipment, labor, and waste removal costs will total approximately \$2,000 per year for an average-sized retailer selling 650 pounds flower equivalent per year, or \$3.07 per pound.

In the higher-security alternative, we assume that a quarantine room of a size averaging approximately 60 square feet per retailer (assuming a 6-foot-by-10-foot space) with video surveillance and a 30-day archive is required, and that cannabis waste must be labeled with a bill of lading or shipping manifest that indicates product information and weight, and is held in the quarantine location for at least 72 hours before being removed from the premises. We estimate that this would cost \$265 per square foot per year to rent, maintain, and operate, including security, surveillance video maintenance, labor and training costs. This is a total of \$15,900 per year per location, or approximately \$24 per pound.

Finally, we estimate the cost of producing compliant badges for all employees at retailers at \$53 per employee per year, based on equipment and materials costs. Assuming 9.4 employees per retailer and 650 pounds produced per retailer, this converts to an overall cost of \$0.76 per pound.

6.4.3 Child-resistant packaging, video surveillance and archive, disposal, and badge compliance costs for the distribution and transportation functions. The largest compliance cost for the distribution function is the cost of child-resistant packaging, as required by MAUCRSA. As the proposed regulations do not increase the cost of meeting this statutory requirement, child-resistant packaging costs are not varied in the alternative packages.

To calculate the compliance cost of child-resistant packaging, we began with the assumption, based on the SRIA prepared for CDPH by Humboldt State researchers, that 30% of total legal cannabis quantity by weight in dried flower equivalent is sold in the form of manufactured products, leaving 70% of total quantity by weight for dried flower sold at retail, for which distributors must bear the costs of packaging and packaging compliance.

Next, we assumed that dried flower would be sold in three package sizes: one-gram, one-eighth-ounce, and one-ounce packages. Although other package sizes for dried flower exist, these are the three most common package sizes sold at retail.

We assumed that 20% of total legal cannabis quantity by weight would be sold in one-gram packages; 35% of total legal cannabis quantity by weight would be sold in 1/8-ounce packages; and 15% of total legal cannabis quantity by weight would be sold in 1-ounce packages.¹⁵⁷ This adds up to 70% of total legal cannabis quantity by weight. (As above, we assumed that the remaining 30% of total quantity by weight would be sold as manufactured cannabis products.) These estimates are highly uncertain, as no quantity-weighted package-size data were available for California's 2017 retail medicinal cannabis market.

Without regulations, dried cannabis flower is still typically packaged into sealable (but non-child-proof) containers. We estimated the cost of packaging without regulations by collecting prices of sealable zip-lock plastic bags from Interplas, a large online wholesaler (Interplas.com). Prices were \$6.90 per 1,000 units (\$0.007 per unit) for 3-inch-by-5-inch zip-lock bags suitable for 1 g dried flower; \$10.70 per 1,000 units (\$0.011 per unit) for 4-inch-by-6-inch zip-lock bags suitable for 1/8 oz dried flower; and \$20.90 per 1,000 units (\$0.021 per unit) for 6-inch-by-9-inch zip-lock bags suitable for 1 oz dried flower.

¹⁵⁷ Here we estimate the quantity per unit of packaging, rather than the quantity per unit of sale. The assumptions in this section are not directly comparable to the assumptions of sales in one-ounce vs. 1/8-ounce quantities that we used to estimate late 2017 average retail prices based on data from the AIC retail price survey. There are several reasons why we expect these two sets of estimates to be different. First, the estimates in this section describe the Taxation Baseline rather than the late 2017 situation. If the most price-elastic consumers are more likely to purchase cannabis by the ounce than other consumers, then we may expect one-ounce demand to be disproportionately represented in the portion of demand that migrates to the illegal market in response to higher legal prices, and we would thus expect to see a shift toward smaller average purchase sizes in the Taxation Baseline and regulated markets. Even in the 2017 situation, the average quantity per unit of packaging is likely to be smaller than average quantity per unit sold. For inventory and distribution reasons, retailers commonly sell cannabis at by-the-ounce prices while still delivering the product to the buyer in multiple smaller package units.

To estimate the cost of compliant packaging, we obtained prices for plastic containers with ASTM-approved child-resistant push-and-turn lids from MarijuanaPackaging.com, a large online wholesaler of compliant cannabis containers. Prices were \$0.25 per unit for compliant one-gram child-resistant plastic containers, \$0.43 per unit for compliant 1/8-ounce child-resistant plastic containers, and \$0.86 per unit for compliant one-ounce child-resistant plastic containers.

Subtracting the total cost of basic zip-lock bags from the total cost of compliant child-resistant containers for each of the three package sizes, we obtained cost differences of \$110.85 per pound for cannabis packaged in one-gram containers, \$53.67 per pound for cannabis packaged in 1/8-ounce containers, and \$13.43 per pound for cannabis packaged in one-ounce containers. We then construct a weighted average for all legal cannabis using our assumptions of 20% of total cannabis quantity being sold in one-gram dried flower packages, 35% in 1/8-oz dried flower packages, and 15% in one-ounce dried flower packages (with no added cost for the 30% of cannabis sold as manufactured products, whose child-resistant packaging costs are already included in the manufacturing compliance costs incorporated into the Taxation Baseline). We calculated our estimate of the child-resistant-packaging compliance cost to distributors of the proposed (as well as lower-cost and higher-security) regulations at \$42.97 per pound.

The video surveillance and archive, cannabis waste storage and disposal, and laminated badge cost calculations described in Sections 6.4.1 and 6.4.2 apply not just to retailers, but also to the distribution and transportation functions described in Section 6.2 and Table 6.2. (We do not consider transporters separately because we anticipate that almost all licensed transporters will also hold other licenses and thus already need to comply.) In order to obtain estimates for these compliance cost inputs for the distribution and transportation functions, as shown in Table 6.2, we note that the costs of compliance in these categories are substantially (though not strictly) fixed per location. For instance, given the small (relative to other agricultural industries) volume per unit value of cannabis, the construction and maintenance of a waste storage container is unlikely to

vary much between an average retailer and an average distributor, even if the distributor has a larger facility and handles 10 times the amount of cannabis as the retailer.

To estimate video surveillance costs, waste storage and disposal costs, and laminated badge costs for the distribution and transportation functions, we thus made the broad assumption that these per-location costs were the same per location as for retailers.

We calculated costs per pound of compliance with video surveillance, waste storage and disposal, and badge regulations for distribution and transportation as follows: we assumed that 650 pounds per year are handled by the average retailer and that there is one distributor for every 10 retailers, with the average distributor thus handling 6,500 pounds per year. Video, disposal, waste storage, and badge compliance costs per pound for distributors are therefore estimated at 10% of those costs for retailers, which totals to \$2.53 per pound, \$5.46 per pound, and \$8.64 per pound in the lower-cost, proposed, and higher-security regulation scenarios.

Including \$42.97 per pound in compliance costs of child-resistant packaging, we thus arrived at total compliance costs for the distribution and transportation functions of \$45.50 per pound, \$48.43 per pound, and \$51.61 per pound in the lower-cost, proposed, and higher-security regulation scenarios.

6.4.4 Retailer delivery compliance costs. Medicinal cannabis deliveries are now typically done by car. However, some urban retailers make deliveries on foot, bicycle, electronic bicycle (e-bike), or scooter at a significant cost savings to the firm.

As of late 2017, delivery costs added approximately \$150 per pound to the retail cost of medicinal cannabis. This calculation relies on an AIC estimate that 40% of product is delivered. We derived this estimate as follows: the AIC retail price survey, as detailed in Appendix Chapter 4 and summarized in Table 4.1, found that 55% of retailers offered in-store sales only, 45% of retailers offered delivery sales only, and 5% of retailers offered both in-store and delivery sales. Accounting for the fact that retailers tend to have larger

annual sales volume than delivery services, we estimated that approximately 40% of cannabis in California is sold via delivery, and 60% is sold via in-store sales.

MAUCRSA statutes do not specify any delivery-method restrictions, and there were none in place as of late 2017, so neither the Taxation Baseline nor our lower-cost alternative generate any additional costs above the basic \$150 per pound delivery cost.

The proposed regulations do not allow any of the lower-cost alternative delivery methods, which, due to their energy efficiency, we would otherwise expect to become more common business practices as the industry moves into the mainstream. As shown in Table 6.6, this restriction would raise the average cost of delivering medicinal cannabis in the state to \$160 per pound, and would raise the cost of cannabis delivery by approximately \$10 per pound compared with the Taxation Baseline delivery cost. However, unenclosed vehicles do not allow as much security as enclosed vehicles. Attaching a lock-box to a person would be impossible, and attaching one to a bicycle or e-bike, or scooter would likely be impractical. With these delivery vehicles allowed, the security objectives of the proposed lock-box regulatory provisions would be ineffective at the delivery stage increasing potential for criminal activity in neighborhoods surrounding cannabis retailers.

A higher-security alternative would be to require two employees to be in each delivery vehicle (one driver and one delivery representative), which would enable one employee to be with the medicinal cannabis inventory at all times. This would provide an additional level of security. The additional labor costs that would result from the higher-security alternative would increase the cost of medicinal cannabis by approximately an additional \$138 per pound compared with the proposed regulations.

Table 6.15 breaks down the calculations and assumptions we use to estimate retailers' delivery compliance costs. Note that these compliance costs apply only to the dispensing function and not to other functions.

Table 6.15. Itemized compliance cost estimates for retail delivery

| Compliance cost variables | Taxation Baseline | Lower-cost alternative | Proposed regulations | Higher-security alternative |
|---|--------------------------|-------------------------------|-----------------------------|------------------------------------|
| On-foot deliveries | | | | |
| Avg distance per on-foot delivery, miles | 1 | 1 | | |
| Avg time per on-foot delivery, hours | 0.5 | 0.5 | - | - |
| Total cost per on-foot delivery, including equip & labor ³ | \$10.80 | \$10.80 | - | - |
| E-bike deliveries | | | | |
| Avg distance per e-bike delivery, miles | 3 | 3 | - | - |
| Avg time per e-bike delivery, hrs | 0.5 | 0.5 | - | - |
| Total cost per e-bike delivery, including equip & labor ³ | \$10.83 | \$10.83 | - | - |
| Car deliveries | | | | |
| Avg distance per car delivery, miles | 5 | 5 | 3 | 3 |
| Avg time per car delivery, hrs | 0.5 | 0.5 | 0.5 | 0.5 |
| Total cost per car delivery, including equip & labor ³ | \$13.63 | \$13.63 | \$12.50 | \$23.30 |
| Overall avg cost per delivery | \$11.75 | \$11.75 | \$12.50 | \$23.30 |
| Avg lbs per delivery ² | 0.03125 | 0.03125 | 0.03125 | 0.03125 |
| Avg cost of delivery per lb delivered | \$376.00 | \$379.18 | \$400.00 | \$745.60 |
| Percent of cannabis delivered statewide ¹ | 40% | 40% | 40% | 40% |
| Total cost of delivery per lb sold | \$150.40 | \$150.40 | \$160.00 | \$298.24 |
| Per lb difference vs. Taxation Baseline | | - | \$9.60 | \$147.84 |

Source: AIC calculations based on industry data.

¹ Assumes 40% of product delivered based on AIC fall 2016 survey and analysis; see Section 6.4.4 for methodology.

² Assumes average delivery of 1/2 oz = 0.03125 lbs per trip (New Frontier, 2017 estimates \$70 per delivery which is approximately 1/2 oz. at current AIC estimates of retail prices).

³ Assumes \$18/hour labor (see Chapter 3) plus 20% administrative time. We assume \$0.01/mile e-bike operating costs and \$0.565/mile car operating costs (the Federal reimbursement rate). Assumes that one-third of deliveries average 1 mile and could be made on foot, one-third of deliveries average 3 miles and could be made by e-bike, and one-third of deliveries average 5 miles and would be made by car.

6.4.5 Hours of operation compliance costs. The proposed regulations provide that cannabis retail businesses may only conduct business between the hours of 6am and 10pm. Until the end of December 2017, there were no state-wide rules for the hours of operation for medicinal cannabis businesses, although some local municipalities imposed restrictions on businesses within their jurisdictions.

In the retail segment, as of December 2017, a significant number of storefront and delivery-only cannabis businesses in California, Colorado, and Washington, did maintain hours after 10pm. In Colorado and Washington, where adult-use and medicinal cannabis regulation is in place, retail businesses are permitted to conduct business from 8 am until midnight.

Although these three states cover the same total number of possible permitted opening hours per day, very few cannabis retailers in any state are open before 8am almost no cannabis retailers in any state are open before 8am. Thus, the relevant difference between California and the other two states is the span between 10pm and midnight. Our detailed data reported below suggest that most post-10pm business in California is conducted between 10pm and midnight, so the effects of the after-midnight restriction in Colorado and Washington is not directly comparable with the potential effects of the after-10pm restriction in California.

As of December 2017, a significant number of cannabis retailers in California were conducting business well after midnight, and some were open 24 hours. *High Times* (2016) reported that 142 different 24-hour cannabis businesses were operating in the state in 2016, 89% of which were in Southern California. For a 24-hour operator, the proposed hours restrictions would curtail 25% (8 of 24) of business hours per day.

Table 6.16. 24-hour medicinal cannabis retailers in California, 2016

| | Storefront | Delivery-only | Total |
|---------------------|-------------------|----------------------|--------------|
| Northern California | 0 | 11 | 11 |
| Central California | 1 | 4 | 15 |
| Southern California | 27 | 99 | 126 |
| Total | 28 | 114 | 142 |

Source: High Times (2016).

In order to get a sense of the importance of hours restrictions on retail businesses, we conducted analysis of hours at 82 cannabis retailers in six municipalities in California (Los Angeles, San Francisco, San Diego, San Jose, Sacramento, and Davis), which is shown in Table 6.16.

The AIC survey found that approximately 63% of retailers in California stayed open after 10pm, and 26% stayed open after midnight. The average closing time of businesses surveyed was 11:51pm. The range of closing times was 8pm to 5am. On average, delivery-only retailers were open later than storefront retailers.

The survey was small and had many areas of uncertainty and potential bias; for instance, the areas surveyed were more urban than rural.

Table 6.17. Businesses impacted by mandatory 10pm closing law: AIC survey of 82 California cannabis retailers in six municipalities, December 2017

| City | Obs. | Hours of currently operating medicinal businesses | | | | |
|--|-----------------------------------|---|---------------------|---|-------------|-------------------|
| | | Avg closing time | Pct open after 10pm | Pct open after midnight | | |
| Los Angeles | 24 | 12:20am | 83% | 33% | | |
| San Francisco | 18 | 10:53pm | 50% | 17% | | |
| San Diego | 16 | 11:56pm | 75% | 38% | | |
| San Jose | 10 | 11:50pm | 30% | 20% | | |
| Sacramento | 8 | 11:08pm | 63% | 13% | | |
| Davis | 6 | 10:40pm | 50% | 17% | | |
| Statewide averages | 82 | 11:51pm | 63% | 26% | | |
| Business hours that would be eliminated by a 10pm curfew | | | | | | |
| City | Avg effect on impacted businesses | | | Effect averaged across all businesses statewide | | |
| | Lost hrs/day | Lost hrs/yr | Pct of total hrs* | Lost hrs/day | Lost hrs/yr | Pct of total hrs* |
| Los Angeles | 2.90 | 1,015 | 21% | 2.42 | 846 | 17% |
| San Francisco | 2.33 | 817 | 19% | 1.17 | 408 | 9% |
| San Diego | 2.75 | 963 | 20% | 2.06 | 722 | 15% |
| San Jose | 4.00 | 1,400 | 33% | 1.20 | 420 | 10% |
| Sacramento | 2.40 | 840 | 19% | 1.50 | 525 | 12% |
| Davis | 1.67 | 583 | 14% | 0.83 | 292 | 7% |
| Statewide averages | 2.71 | 949 | 20% | 1.72 | 602 | 13% |

*Assumes uniform state-wide average opening time of 10:30am.

Source: AIC survey

If the estimates in Table 6.17 are accurate indicators of California-wide averages, then one could potentially infer that 63% of businesses in the state would have to change their hours in order to comply with the 10pm closing restriction. The number of lost work hours can be estimated by assuming that all retailers that were open later than 10pm on December 2017 would change to closing at 10pm under the proposed Bureau regulations. Lost hours of access for buyers are calculated as the amount of time after 10pm that the store was previously open and would now have to be closed.

Average lost hours per affected retailer (i.e. the 63% of retailers that were previously open later than 10pm) was approximately 2.71 hours per day and 949 hours per year per affected business, and average lost hours per cannabis business overall, including all cannabis retailers in the state, was 1.72 hours per day and 602 hours per year, or 13% of total business hours in the state.

Estimating the main economic impact of the hours-of-operation restriction on legal cannabis sales, is difficult for several reasons. First, reliable data are not available on the distribution of sales over the course of the day at cannabis retailers, so it is not clear what percent of total sales are made during the 13% of total open retail hours in the state that happen after 10pm.

It is even more difficult to predict is how consumers are likely to react to the unavailability of legal retail cannabis in the late-night hours. Some will simply plan ahead and buy their cannabis earlier (“inter-temporal substitution,” in economic terms), whereas some will instead substitute illegal cannabis for the legal cannabis they would otherwise have bought.

Some research has suggested that drug addicts tend to experience intense immediate cravings. Addicts tend to buy their products of choice wherever it is available during the short time horizon in which the craving occurs. If this is applicable to a significant amount of cannabis sales, users who were previously able to buy legally between 10pm and 4am would likely seek cannabis from the illegal market after 10pm. seek the illegal market if legal product is not available at a particular time of day. Cannabis consumers may also turn to other purchases. Some research shows a substitution effect between cannabis and opiates such as OxyContin and oxycodone.

With respect to non-medical consumption, there is credible evidence that alcohol and cannabis are, to some extent, substitutes (although there is also a minority of evidence suggesting that they are substitutes). If there is a substitution effect, the unavailability of cannabis after 10pm could cause more alcohol consumption after 10pm.

These effects are, once again, extremely difficult to quantify, and few existing precedents make for useful comparisons. There are certain retail hours restrictions for the sale of tobacco and alcohol in California, especially in local municipalities, but none, to our knowledge, that affect sales before midnight.

For illustrative purposes, we consider nine possible outcomes that could result from varying two different assumptions and their potential impacts on cannabis transactions between 10pm and 6am. These possible outcomes are considered in Table 6.9.

The three rows in Table 6.9 vary the assumption about what percent of cannabis is sold during late-night hours. The midpoint (13%) assumes that the average sales per hour during late-night hours is the same as average sales per hour during other open hours. The low and high estimates are 50% and 200% of this assumption, respectively.

The three columns in Table 6.18 vary the assumption about intertemporal elasticity of substitution, i.e. what percent of consumption migrates to the illegal market during late-night hours if legal cannabis is not available. As intertemporal elasticities are particularly difficult to predict for the cannabis market, we choose a wide range of values, from 5% to 50%. The overall impacts thus cover a very large interval, from 0.3% to 13% of the total legal cannabis market.

Table 6.18. Potential shifts from legal to illegal market due to late-night hours restrictions

Percentages of quantity lost due to illegal substitution given certain substitution and post-10pm sales frequency assumptions

| Assumption about sales frequency after 10pm | Intertemporal substitution assumption | | |
|--|---|---|--|
| | <i>50% of late-night sales move to illegal market</i> | <i>20% of late-night sales move to illegal market</i> | <i>5% of late-night sales move to illegal market</i> |
| 6.5% of sales occur between 10pm-6am (assumes daytime sales rates are higher than daytime sales rates) | 3.3% of total market moves to illegal | 1.3% of total market moves to illegal | 0.3% of market moves to illegal |
| 13% of sales occur between 10pm-6am (assumes nighttime and daytime sales rates are equal) | 6.5% of total market moves to illegal | 2.6% of total market moves to illegal | 0.7% of total market moves to illegal |
| 26% of sales occur between 10pm-6am (assumes nighttime sales rates are higher than daytime sales rates) | 13% of total market moves to illegal | 5.2% of total market moves to illegal | 1.3% of total market moves to illegal |

Consumer responses to restricted hours are complex and fall into three broad categories:

- (4) Some demand would shift to earlier hours. We would expect buyers who purchase large package sizes for their monthly use, for example, would continue to buy from their preferred source and shift to earlier in the day.
- (5) Other buyers that had less flexibility over time would not purchase cannabis at all, and shift their demand to some other product (say alcohol) that is available during the late evening hours when legal cannabis is unavailable.
- (6) Some demand would shift to the unlicensed or illegal cannabis segment, which is not limited by hours of operation.

It is hard to gauge the relative importance of these responses. In our simulations we shift demand for both segments of legal cannabis back by 2% due and shift demand for illegal cannabis out by 1.5% due to the hours restrictions. This assumption implies that much of the quantity purchased during the hours where legal operation is no longer available shifts to available hours and remains in the legal segment.

One reason for that response is that buyers with flexibility across segments and with easy access to the illegal segment are likely to have already chosen this lower priced option. Furthermore, as with other products, a high proportion of cannabis quantities are likely to be purchased by consumers who buy their weekly or monthly supply in large purchases to take advantage of volume discounts and this behavior indicates a degree of advanced planning. This is an additional significant source of uncertainty in our projections.

Both the costs and the countervailing benefits of hours restrictions are hard to quantify. No reliable evidence on the costs or benefits of a 10pm cannabis sales hours restriction is available, in part because no comparable state jurisdiction has experimented with hours

regulations as restrictive as California's. The potential safety benefits to California could include a reduction in public nuisances such as street noise or the illegal public consumption of cannabis in the proximity of storefront retailers after 10pm, which may disturb local residents. The potential safety costs, which are equally difficult to hard to quantify, could include an increase in criminal activity due to the shift to the illegal market for all transactions after 10pm.

6.5 License fees and summary compliance costs

A summary of the costs of the package of proposed and alternative packages of regulations is provided in Table 6.10. Testing is by far the most costly component of the proposed regulations, accounting for approximately two-thirds of total compliance costs.

Track and trace, surveillance video archival, and waste storage disposal, and other expenses also add to compliance costs. They are included in the "Other retail compliance" component of Table 6.19.

Note that hours of operation restrictions are not included in the cost per pound calculations in Table 6.19, but rather are represented as demand curve shifts and thus accounted for in AIC simulations.

Table 6.19. Estimated compliance costs per pound of alternative regulatory packages

| Cost/lb dried-flower equivalent | Lower-cost alternative | Proposed regulations | Higher-security alternative |
|--|---|----------------------|-----------------------------|
| License fees, distribution | \$4 | \$4 | \$4 |
| License fees, microbusiness and retail | \$40 | \$40 | \$40 |
| Distribution and transport compliance, including child-resistant packaging | \$46 | \$48 | \$52 |
| Retail-delivery-methods restrictions | None | \$10 | \$148 |
| Other retail compliance, including surveillance video archival, track-and-trace and other MAUCRSA-mandated regulations | \$25 | \$49 | \$86 |
| Testing compliance, including cost of licenses, pre-testing, testing and remediation, labeling, plus inventory lost due to testing samples and failed tests ¹ | \$235 | \$257 | \$414 |
| Hours of operation restrictions | Not calculated on a per-pound basis. Included in simulation as: (1) a -2% shift in demand in medicinal cannabis segment; (2) a -2% shift in demand in adult-use cannabis segment; and (3) a +1.5% shift in demand in illegal cannabis segment. See Section 6.4.6 for details. | | |
| Total compliance costs per pound | \$350 | \$408 | \$744 |

Notes: Numbers were rounded to the nearest \$1. See Appendix Chapter 6 for details. Cost components do not add up exactly to total costs, because of rounding.

¹See Table 4 for details.

7. Modeling the Effects of Shifts Caused by Legalization and Taxation, and Regulations in Cannabis Demand and Supply on Three Segments of Cannabis Prices and Quantities

The model outlined below first characterizes demand for cannabis in a form amenable to simulation. Next, we explain a simplified supply side of cannabis sales to consumers. We then discuss the solution for effects of changes to the cannabis market: first, with the introduction of adult-use sale legalization and state and local taxation, and second, with the introduction of regulations. This chapter is necessarily more technical and contains more mathematical notation than other chapters of this report.

We focus on three cannabis segments as they will be in place after adult-use sale legalization, taxation, and regulation in place in 2018: medicinal, adult-use, and illegal. These segments do not refer to who possesses or consumes the cannabis. Clearly, some cannabis that is produced and sold in the medicinal segment might be used by someone without medicinal permission, and cannabis that is sold in the adult-use segment might be used by someone under the age of 21. Our segment definitions relate solely to the segment through which the cannabis is produced and sold.

The chapter develops an approach that allows a manageable simulation model for the impacts of regulation of medicinal and adult-use cannabis. We also use the approach to discuss the impacts that create the Taxation Baseline, but without yet applying the Bureau regulations that are the subject of the regulatory impact analysis. As discussed above, the hypothetical baseline situation is required because the regulations of interest will be applied to a market that is substantively different from the late 2017 market, in which adult-use sale is not permitted and cannabis-specific taxes are not generally in place.

7.1 Demand

The model of consumer demand for cannabis is based on a two-stage budgeting process developed in Deaton and Muellbauer (1980a, 1980b). The first stage generates a system of individual demand functions for the allocation of total expenditure among commodity categories. The second stage of the two-stage allocation generates a system of individual segment-specific demand functions within the cannabis commodity group. A comprehensive review of the literature on two-stage budgeting can be found in Deaton (1986). The first stage models of demand for cannabis as a whole. In the second stage, demand for segment-specific cannabis is modeled conditional on the total cannabis expenditure across all segments determined in the first stage.

The two-stage budgeting approach is widely used in demand simulations. Since the number of own-price and cross-price elasticities of demand increases with the square of the number of commodities, the complexity of the simulation and requirement for estimated or assumed parameters expands similarly. Under the two-stage budgeting and accompanying assumptions, the number of products can be kept relatively small. This approach offers considerable empirical convenience. The key assumption here is that cannabis (the group of the individual cannabis segments) has demand relationships with other goods as an aggregate. Theoretical consistency of the model requires developing an aggregate cannabis group price index and some conditions on consumer demand behavior between cannabis and all other goods.

Following the suggestion in Deaton and Muellbauer (1980b), we developed the aggregate cannabis price index using the Stone (1954) price index method. To derive segment-specific elasticities, we specify demand substitution parameter values. These values are developed based on data, previous studies and researcher judgments described below.

To focus on the application at hand, we first note that the medicinal cannabis segment is distinct in access from what has been the illegal cannabis segment. The prices and quantities in this segment are designated with subscript “m.” Second, we note that the

non-medicinal part of the market will separate into two segments upon the legalization of adult-use sale. The prices and quantities in the newly legal adult-use segment will be designated with the subscript “a”. Finally, in the segment that remains illegal, prices and quantities will be designated with the subscript “i.”

Let us begin with the utility function expressed as (1), with notation shown in Table 11.1 for easy reference:

$$\text{Total utility function: } u = U(Q^c, Q^o) \quad (1)$$

Equation (2) defines the price of aggregate cannabis in terms of three cannabis segments' prices, $\ln P_j$, and market shares, w_j :

$$\text{Stone's price index: } \ln P^* = \sum_{\{j=i\}}^{\{i,a,m\}} w_j \ln P_j \quad (2)$$

Equation (3) defines the aggregate quantity in terms of the quantity of each segment (illegal, legal adult-use and legal medicinal):

Aggregate quantity demanded for cannabis:

$$Q_c = Q_i + Q_a + Q_m \quad (3)$$

The following assumptions are used:

- a) Demand for cannabis is weakly separable from other goods in the demand system. The weak separability assumption can be represented by $U(Q^c, Q^o) = F(u_c(Q^c), u_o(Q^o))$, where U is the utility function of consuming all goods, Q^c is the quantity vector for cannabis group, $u_c(Q^c)$ is the sub-utility function associated with cannabis consumption, and Q^o is the quantity vector for any other products, $u_o(Q^o)$ is the sub-utility function associated with consumption of products other than cannabis, and F is an increasing function in all its arguments.

b) The total cost of living (TCOL) is independent to sub-utility level (Edgerton, 1997; Carpentier and Guyomard, 2001), i.e. that the empirical variation of $P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I, u_I) \cong P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I)$, $\forall I = c, o$, where I is the product group index, P^I is the index for total cost of living, \mathbf{p}^I is the price vector for group I , $\bar{\mathbf{p}}^I$ is the base period prices for group I , u_I is the sub-utility of consumption for group I . The product group indices include cannabis (c) and non-cannabis products (o). This capital “I” is not related to the lower-case “i” that represents the illegal cannabis segment within c.

Given the weak separability assumption, the group allocation problem can be defined as

$$\text{Max}_{\{u_c, u_o\}} F(u_c, u_o)$$

$$\text{s.t. } M = \sum_{I=c}^{c,o} c_I(\mathbf{p}^I, u_I),$$

where u_I is the value of the sub-utility function for group I , M is the total expenditure, \mathbf{p}^I is the price vector for group I , $c_I(\mathbf{p}^I, u_I)$ is the cost function associated to the sub-utility function $u_I(\mathbf{q}^I)$.

The cost of consuming group I at price \mathbf{p}^I can be rewritten as

$$c_I(\mathbf{p}^I, u_I) = c_I(\bar{\mathbf{p}}^I, u_I) \frac{c_I(\mathbf{p}^I, u_I)}{c_I(\bar{\mathbf{p}}^I, u_I)} = c_I(\bar{\mathbf{p}}^I, u_I) P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I, u_I), \forall I = c, o,$$

where $P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I, u^I)$ is the true cost of living price index (TCOL price index) and $c^I(\bar{\mathbf{p}}^I, u^I)$ can be thought of as a quantity index (Carpentier and Guyomard, 2001). By assuming the TCOL price index is approximately independent with subutility u^c and u^o , i.e. $P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I, u_I) \cong P^I(\mathbf{p}^I, \bar{\mathbf{p}}^I)$, we can rewrite the utility maximization problem as

$$\text{Max}_{\{c_c, c_o\}} \Phi(c_c(\bar{\mathbf{p}}^c, u_c), c_o(\bar{\mathbf{p}}^o, u_o))$$

$$s.t. M = \sum_{I=c}^{c,o} c_I(\bar{P^I}, u_I) P^I(P^I, \bar{P^I}),$$

where the Φ is the modified utility function in terms of quantity indices for cannabis and other goods, $c_I(\bar{P^I}, u_I)$ is the quantity index for group I, and $P^I(P^I, \bar{P^I})$ is the total cost of living.

For example, based on Carpentier and Guyomard's (2001) result, the unconditional elasticity of demand for medicinal cannabis and the cross-price demand elasticity between medicinal and illegal cannabis, using an approximation to the Slutsky substitution term, could be approximated in general forms as follows, where we illustrate the expressions with the own elasticities for medicinal cannabis and the cross effects between medicinal and illegal cannabis.

The unconditional expenditure elasticity for medicinal cannabis is: $\eta_{mY} = \eta_{mY}^c \eta_{cM}$.

The unconditional Hicksian demand elasticity for medicinal cannabis is:

$$\eta_{mm}^* = \eta_{mm}^{*c} + w_m \eta_c^* \eta_{mY}^c \eta_{mY}^c.$$

The unconditional cross-price Hicksian demand elasticity between medicinal and illegal cannabis is:

$$\eta_{mi}^* = \eta_{mi}^{*c} + w_i \eta_c^* \eta_{mY}^c \eta_{mY}^c.$$

The unconditional Marshallian demand elasticity for medicinal cannabis is:

$$\eta_{mm} = \eta_{mm}^c + w_m \left(\frac{1}{\eta_{mY}^c} + \epsilon^* \right) \eta_{mY}^c \eta_{mY}^c + w_m s_c \eta_{cM} \eta_m^c (\eta_{mY}^c - 1).$$

And, the unconditional cross-price Hicksian demand elasticity between medicinal and illegal is:

$$\eta_{mi} = \eta_{mi}^c + w_i \left(\frac{1}{\eta_{iY}^c} + \epsilon^* \right) \eta_{mY}^c \eta_{iY}^c + w_i s_c \eta_{cM} \eta_m^c (\eta_{iY}^c - 1),$$

where the subscripts m, i, and a represent cannabis segments, medicinal, illegal and adult-use. η_{jk} with $j, k = m, i, a$, represents the cross-price Marshalian demand elasticity between group j and k. η_{jk}^* with $j, k = m, i, a$, represents the cross-price Hicksian demand elasticity between group j and k. The subscript Y represents the cannabis group expenditure. η_{jY} with $j = m, i, a$, represents the expenditure elasticity for group j. The subscript c represents the whole cannabis group. Elasticity η_c^* represents the Hicksian demand elasticity for cannabis group. The elasticity ϵ^* represents the Marshalian demand elasticity for cannabis group. The superscript c means the parameter is conditional on the group expenditure and s_c is the expenditure share of cannabis of the total income.

If we assume homothetic preferences and a unit conditional expenditure elasticity (Edgerton, 1997), we could rewrite the above equation as follows.

The unconditional expenditure elasticity for medicinal cannabis is:

$$\eta_{mY} = \eta_{cM}.$$

The unconditional Hicksian demand elasticity for medicinal cannabis is:

$$\eta_{mm}^* = \eta_{mm}^{*c} + w_m \eta_c^*.$$

The unconditional cross-price Hicksian demand elasticity between medicinal and illegal cannabis is:

$$\eta_{mi}^* = \eta_{mi}^{*c} + w_i \eta_c^*.$$

The unconditional Marshalian demand elasticity for medicinal cannabis is:

$$\eta_{mm} = \eta_{mm}^c + w_m(1 + \epsilon^*) . \quad (4)$$

The unconditional cross-price Marshallian demand elasticity between medicinal and illegal cannabis is:

$$\eta_{mi} = \eta_{mi}^c + w_i(1 + \epsilon^*) . \quad (5)$$

We can rewrite equations (4) and (5), using conditional Slutsky equation under unit conditional expenditure elasticity, $\eta_{mm}^c = \eta_{mm}^{*c} - w_m$, and $\eta_{mi}^c = \eta_{mi}^{*c} - w_i$, and the conditional Hicksian cross-elasticity of demand, $\eta_{kj}^{*c} = w_j \sigma_{kj}^c$, where σ_{kj}^c is the conditional elasticity of substitution of group j and k, with the homogeneity condition, which implies in the three factor case, $\eta_{mm}^{*c} = -\eta_{mi}^{*c} - \eta_{ma}^{*c}$, and the symmetry condition, $\sigma_{im} = \sigma_{mi}$, as:

$$\eta_{mm} = -w_i \sigma_{mi}^c - w_a \sigma_{ma}^c + w_m \epsilon^* \text{ and} \quad (6)$$

$$\eta_{mi} = w_i \sigma_{mi}^c + w_i \epsilon^*. \quad (7)$$

7.2 The supply side and simulation model of the changes in quantities and prices in the market

We begin with a set of initial prices and quantities in the three segments to which proportional changes to the demand function and parameters and the supply function and parameters applied. The medicinal segment initial prices and quantities were developed from recent data as described in detail in other sections of this report. As an initial starting point for discovering equilibrium prices and quantities, we assumed that the current market is separated into two segments: first is the segment "a", which includes that quantity demanded and supplied in the legal adult-use segment, and segment "i", which includes that quantity of cannabis in the illegal segment.

We assume initially that after taxation and adult-use sale legalization (the Taxation Baseline), legal and illegal have equal quantities, and that within legal, 600,000 pounds is medicinal and 700,000 is adult-use. We can think of this as initially 650,000 pounds moving into adult-use from illegal and 50,000 moving from medicinal to adult-use. We set the initial price in the newly legal adult-use segment as equal to the initial medicinal retail price, and the price in the continuing illegal segment as 35% below the medicinal retail price to reflect the best information available for prices in 2017. These initial situation choices do not represent a baseline used for the regulation analysis and are not crucial to defining the Taxation Baseline (which represents the situation that would exist with taxes and costly local and other non-Bureau regulations).

From the initial situation we explore proportional changes from the demand side and supply side on each segment to generate the Taxation Baseline. On the demand side, the quantity demanded for segment-specific cannabis changes, α , which is a vector of quantity changes in percentage terms, when holding the prices and total expenditure constant.

Based on the unconditional own-price and cross-price elasticity, we can approximate the changes in quantity and total revenue for segment-specific cannabis, as:

$$dlnQ_m^d = \eta_{mm} dlnP_m^d + \eta_{ma} dlnP_a^d + \eta_{mi} dlnP_i^d + \alpha_m \quad (8)$$

$$dlnQ_a^d = \eta_{am} dlnP_m^d + \eta_{aa} dlnP_a^d + \eta_{ai} dlnP_i^d + \alpha_a \quad (9)$$

$$dlnQ_i^d = \eta_{im} dlnP_m^d + \eta_{ia} dlnP_a^d + \eta_{ii} dlnP_i^d + \alpha_i \quad (10)$$

In these equations, the superscript d represents the variables on the demand side. For example, $dlnQ_m^d$ represents the change of quantity demanded for medicinal cannabis.

As with the demand side of the market, the supply side of the model focuses on the retail prices and quantities. This application of the model for the impact analysis includes shifts

in costs that apply to wholesale and retail functions, including product transportation and testing. Thus, we take any changes at the farm and processing level of the production process as exogenous, and we do not explore those changes in any detail.

On the supply side, the cost of production changes by β , which is a vector of cost shifts for segment-specific cannabis. Ad valorem taxes t apply to retail revenue in two segments. Among parameters required are the supply elasticities for the three segment-specific cannabis marginal cost functions. We then approximate the change in prices facing suppliers with tax included, as:

$$d\ln P_m^s = \frac{d\ln Q_m^s}{\xi_m} + \beta_m + t_m \quad (11)$$

$$d\ln P_a^s = \frac{d\ln Q_a^s}{\xi_a} + \beta_a + t_r \quad (12)$$

$$d\ln P_i^s = \frac{d\ln Q_i^s}{\xi_i} + \beta_i + t_i \quad (13)$$

where the superscript s represents the variables on the supply side. For example, $d\ln P_m^s$ represents the price change of medicinal cannabis for suppliers. ξ_j with $j = m, a, i$ represents the supply elasticity for group j .

Notice that these marginal cost specifications already incorporate the price equals marginal cost equilibrium condition and are specified as vertical shifts in the supply function reflecting per unit costs. Equations (8) to (13) and the market equilibrium conditions are used in simulations to investigate how shifts in costs and demand affect prices and quantities of cannabis and prices and quantities of medicinal, legal adult-use and illegal cannabis. Parameters include shares, own-price and cross-price demand elasticities, and supply elasticities.

7.3 Illustration of demand shifts in the cannabis market due to adult-use legalization

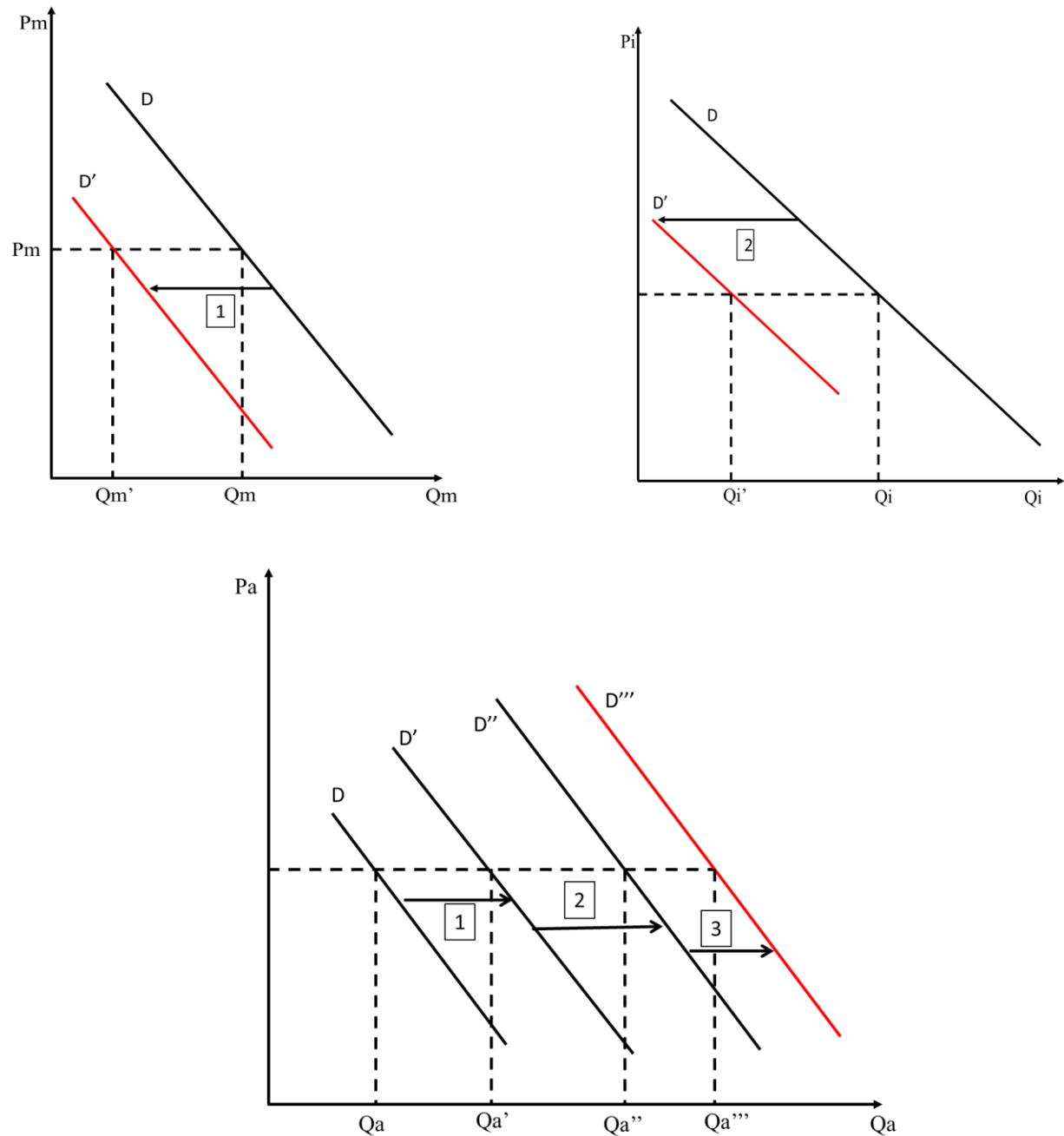
This section illustrates the potential shifts in cannabis demand by segments that accompanies legalization of adult-use cannabis. The top left panel of Figure 7.1 shows a shift back in the demand in the medicinal segment from D to D' that accompanies the legalization of adult-use cannabis. This occurs because previous medicinal cannabis buyers can avoid the added costs of acquiring a medicinal recommendation by now buying in the adult-use segment. This suggests that allowing legal sale of adult cannabis will decrease the demand for medicinal cannabis.

The top right panel of Figure 7.1 shows a shift back from D to D' in the quantity of cannabis sold in the illegal segment as some buyers leave the illegal segment for the newly legal non-medicinal adult-use segment.

The bottom panel of Figure 7.1 shows the initial position of demand for adult-use cannabis that accompanies adult-use legalization represented by demand D and quantity Q_a . We could set this quantity equal to zero to characterize the definition that the segment does not exist until legalization. Alternatively, this initial quantity could represent a small amount of cannabis that immediately participates in the adult-use segment.

The first two shifts out in the demand for adult-use are analogs to the shifts inward in demand for medicinal and adult-use cannabis shown the first two panels of figure 7.1. The reduction in demand shown in the top left panel is represented in the bottom panel by the shift out in demand for adult-use cannabis from D to D'. The reduction in illegal cannabis illustrated in the upper right panel of Figure 7.1 is shown in the bottom panel as a further increase in demand for adult-use cannabis from D' to D''. Finally, an increase in demand from buyers who previously did not purchase cannabis in either the medicinal or illegal segments, but now enter the adult-use segment is shown in the shift from D'' to D''''. This demand shift could be due to an increase of cannabis sold to residents or cannabis sold to visitors who were previously not eligible to buy cannabis in the medicinal segment.

Figure 7.1. Demand shifts in medicinal, illegal, and adult-use cannabis markets that accompany adult-use legalization



7.4 Solving for implied tax rate for the simulation model

The laws that set out legalization of adult-use cannabis included a percentage tax rate t_t on the retail revenue of medicinal and adult-use cannabis. In order to solve for the impact of that percentage tax rate on prices, quantities and implied revenue, we solve for the equivalent initial (pre-change) tax rate as a percentage of prices that would occur without adult-use legalization. The tax rate equivalent is used in equations (11) to (13) to simulate impacts.

Let us begin with the total revenue for medicinal cannabis after the legalization of adult-use cannabis as shown in equation (14). The medicinal cannabis faces a tax rate t_b before adult-use legalization. Adult-use legalization imposes t_m tax rate on top of the initial price P_0 as follows:

$$\text{Total tax revenue: } R_t = Q_1 P_0 \cdot (t_m + t_b). \quad (14)$$

The revenue excluding tax and target tax rate can be written as a function of the new price P_1 :

$$\text{Revenue without tax: } R_{-t} = Q_1 P_1 - Q_1 P_0 \cdot (t_m + t_b). \quad (15)$$

$$\text{Target tax rate: } t_t = \frac{Q_1 P_0 (t_m + t_b)}{Q_1 P_0 (1 + dlnP - t_m - t_b)} \quad (16)$$

By rearranging equation (16), we obtain equation (17) indicating the relationship of the target adult-use legalization tax rate, t_t , and the imposed tax rate, t_m , in terms of initial price.

$$(1 + t_t)t_m - t_t dlnP = t_t(1 - t_b) - t_b \quad (17)$$

We can extend the approach for adult-use cannabis. Because of adult-use legalization, adult-use cannabis faces an increase in tax rate from zero to t_t at the outcome. In terms

of the initial prices before adult-use legalization, the tax rate is t_a . Equation (18) represents the relationship between the target tax rate and the tax rate in terms of initial price.

$$(1 + t_t)t_a - t_t dlnP = t_t \quad (18)$$

The illegal cannabis faces no tax. Together with (17) and (18), we have the following equations:

$$(1 + t_t)t_m - t_t dlnP_m = t_t(1 - t_b) - t_b \quad (19)$$

$$(1 + t_t)t_a - t_t dlnP_a = t_t \quad (20)$$

$$t_i = 0 \quad (21)$$

7.5 Solution matrix

We now have a system of equations including equations (8) to (13), equations (19) to (21), and market equilibrium conditions. We will use this system of equations to solve for the price and quantity changes for each specific cannabis segment. A simplified matrix is shown below and the solution could be solved as the product of the inverse of matrix M and vector b , where matrix M is the coefficient matrix on the left hand side and b is the dependent matrix on the right hand side. The solution is in terms of supply and demand elasticities, the target tax rate, and the demand function and parameter changes and supply function and parameter changes.

$$\underbrace{\begin{bmatrix} \eta_{mm} - \xi_m & \eta_{ma} & \eta_{mi} & \xi_m & 0 & 0 \\ \eta_{am} & \eta_{aa} - \xi_a & \eta_{ai} & 0 & \xi_a & 0 \\ \eta_{im} & \eta_{ia} & \eta_{ii} - \xi_i & 0 & 0 & \xi_i \\ -t_t & 0 & 0 & 1 + t_t & 0 & 0 \\ 0 & -t_t & 0 & 0 & 1 + t_t & 0 \\ 0 & 0 & 0 & 0 & 0 & 1 \end{bmatrix}}_M \underbrace{\begin{bmatrix} dlnP_m^d \\ dlnP_a^d \\ dlnP_i^d \\ t_m \\ t_a \\ t_i \end{bmatrix}}_x = \underbrace{\begin{bmatrix} -\alpha_m - \xi_m \beta_m \\ -\alpha_a - \xi_a \beta_a \\ -\alpha_i - \xi_i \beta_i \\ t_t(1 - t_b) - t_b \\ t_t \\ 0 \end{bmatrix}}_b$$

Solution: $x = M^{-1}b$

The quantity change $dlnQ_{j=m,a,i}$ for segment-specific cannabis can be obtained from equations (8) to (10). The aggregate quantity change $dlnQ_c$ is the weighted sum of the three segment-specific cannabis quantity changes. As an alternative, we could also derive the aggregate quantity change, $dlnQ_c = \epsilon^* dlnP^* + \alpha^*$, where $dlnP^* = \sum_{j=i}^{i,m,a} w_j dlnP_j$, and $\alpha^* = \sum_{j=i}^{i,m,a} w_j \alpha_j$.

7.6 Individual segments and the change in revenue

We consider supply-side shifts (the change in marginal cost) and demand-side shifts (the change in the quantity purchased at a given price the medicinal, adult-use, and illegal cannabis). We must also include the cross effects between the different segments. Shifts affect the relative prices in cannabis segments, and this impact shifts each segment's demand because of substitution effect over cannabis segments.

Based on the quantity and price changes of cannabis, we can approximate the total revenue change. Here we will illustrate the total revenue change and consumer surplus change in the medicinal segment as an example. The change of the total revenue for the medicinal segment is the sum of the proportional changes in medicinal price and the quantity and their product, based on $dlnTR_m = dln(P_m \cdot Q_m)$, as, $dlnTR_m = dlnP_m + dlnQ_m + dlnP_m \cdot dlnQ_m$

7.7 Change in the aggregate total revenue

Based on the aggregate quantity of demand effects and the price-index change for cannabis, we can write the change of total revenue in cannabis segment as the sum of the change in total quantity and price index:

$$dlnTR_c = (\epsilon^* dlnP^* + \alpha^*) dlnP^* + (\epsilon^* + 1) dlnP^* + \alpha^*, \text{ where } dlnP^* = \sum_{j=i}^{i,m,a} w_j dlnP_j,$$

and $\alpha^* = \sum_{j=i}^{i,m,a} w_j \alpha_j$.

As an alternative, the aggregated revenue change is just the weighted sum of the individual revenue changes from each segment, as $dlnTR_c = \sum_{j=i}^{i,m,a} w_j dlnTR_j$.

Table 7.1. Summary of notation used in derivation and discussion of simulation

| <i>Notation</i> | <i>Description</i> |
|--|--|
| $Q^I (I = c, o)$ | The quantity vector for cannabis group and other goods. |
| $u_I (I = c, o)$ | The sub-utility function of consuming cannabis and other goods. |
| $\mathbf{p}^I (I = c, o)$ | The price vector for cannabis and other goods. |
| $\overline{\mathbf{p}}^I (I = c, o)$ | The base-period price vector for cannabis and other goods. |
| $c_I (I = c, o)$ | The cost function for cannabis and other goods. |
| Q_c | Quantity of cannabis. |
| P^* | The Stones' price index of cannabis group. |
| P^o | The price of composite goods which includes all other products in the demand system. |
| M | Total income. |
| $P_j (j = i, a, m)$ | The prices of illegal (i), adult-use legal adult-use (a), and medicinal (m) cannabis. |
| $w_j (j = i, a, m)$ | The within-group expenditure share of illegal, adult-use, and medicinal cannabis. They sum to 1. |
| $Q_j (j = i, a, m)$ | The quantities of illegal, adult-use, and medicinal cannabis. |
| Y^c | Total expenditure on cannabis. |
| ϵ^* | The total own-price elasticity of demand for cannabis. |
| $\xi_j (j = i, a, m)$ | The supply elasticity for illegal, adult-use, and medicinal cannabis. |
| η_{jj} ($jj = ii, aa, mm$) | The unconditional own-price Marshallian elasticity of demand for illegal, adult-use, and medicinal cannabis. |
| η_{jj}^c ($jj = ii, aa, mm$) | The conditional own-price Marshallian elasticity of demand for illegal, adult-use, and medicinal cannabis. |
| η_{jj}^* ($jj = ii, aa, mm$) | The unconditional own-price Hicksian elasticity of demand for illegal, adult-use, and medicinal cannabis. |

| | |
|---|--|
| η_{jj}^{c*} ($jj = ii, aa, mm$) | The conditional own-price Hicksian elasticity of demand for illegal, adult-use, and medicinal cannabis. |
| η_{jk} ($jk = ma, mi, ai, am, ia, im$) | The unconditional cross-price Marshallian elasticity of demand within the group of medicinal, adult-use, and illegal cannabis. |
| η_{jk}^c ($jk = ma, mi, ai, am, ia, im$) | The conditional cross-price Marshallian elasticity of demand within the group of medicinal, adult-use, and illegal cannabis. |
| η_{jk}^* ($jk = ma, mi, ai, am, ia, im$) | The unconditional cross-price Hicksian elasticity of demand within the group of medicinal, adult-use, and illegal cannabis. |
| η_{jk}^{c*} ($jk = ma, mi, ai, am, ia, im$) | The conditional cross-price Hicksian elasticity of demand within the group of medicinal, adult-use, and illegal cannabis. |
| η_{jY}^c ($j = i, a, m$) | The conditional expenditure elasticity of demand for illegal, adult-use and medicinal cannabis. |
| σ_{jk}^c ($jk = ma, mi, ai, am, ia, im$) | The conditional elasticity of substitution within the group of medicinal, adult-use, and illegal cannabis. |
| η_{cM} | The unconditional income elasticity of demand for cannabis. |
| η_c | The Marshallian demand elasticity for cannabis group |
| η_c^* | The Hicksian demand elasticity for cannabis group |
| α_j ($j = i, a, m$) | The demand shift for illegal, adult-use, and medicinal cannabis. |
| β_j ($j = i, a, m$) | The marginal cost shift for illegal, adult-use, and medicinal cannabis. |
| t_t | The target tax rate after adult-use legalization. |
| t_j ($j = i, a, m$) | The imposed tax rate in terms of the pre-adult-use-legalization price. |

7.8 Further demand considerations: addictive behavior and Becker approach to drug demand

We refer here to the addictive behavior approach introduced by Becker and Murphy (1988) regarding drug consumption, which is also discussed in Grossman and Chaloupka (1998) and Becker et al. (2006). This approach assumes that addicts behave rationally and emphasizes the interdependency of past, current, and future consumption of an addictive

good. This indicates that consumers incorporate the effects of current consumption on future utility. This approach is generally consistent with our modeling, but we make no particular assumption about effects of habits.

For any illegal activity, a component in determining substitution between the uses is the level of enforcement for the remaining illegal production, sale and use. Becker et al. (2006) modeled the linkage between the elasticity of demand for an illegal good and the effects of enforcement against illegal goods, and thus the overall size of the illegal market. We recognize this relationship. However, although changes in enforcement of the remaining illegal market may shift marginal cost, we do not model them as changing elasticities of supply or demand in this study.

7.9 Literature on empirical estimates of the own-price elasticity of demand for cannabis

The empirical literature on the effects of price on the use of addictive drugs such as cocaine, cannabis, and heroin is sparse. Nisbet and Vakil (1972) estimated a price elasticity of demand for cannabis ranging from -0.36 to -1.51 using an anonymous mail-in survey of students at the University of California at Los Angeles. Lakhdar, Vaillant and Wolff (2016) also estimated a cannabis price elasticity for demand using 250 French users in 2005. Their elasticity estimates were between -1.7 and -2.1, which were relatively high compared to those found in other studies.

The price elasticity estimates by Pacula et al. (2001) using high school seniors ranged between -0.002 to -0.69. Van Ours and Williams (2007) examined cannabis use by young Australians, and their elasticity estimates ranged between -0.31 and -0.70. Most recently, Jacobi and Sovinski (2016) conducted an empirical cannabis study using the Australian National Drug Household Survey, which was published in the *American Economic Review*. Their estimate for price elasticity was -0.2, and we adopt this value to derive cross-price elasticities. Unlike other studies, Jacobi and Sovinski (2016) used data from the broad population of cannabis users, which is one reason we adopt this value.

7.10 Assumptions about the elasticities of demand for cannabis and cannabis segments

To project the changes in quantity demanded in the three cannabis segments, it is critical to assess consumer substitution between these uses. To evaluate substitution behavior and ultimately the quantity changes, we rely on previous studies, empirical data, and economic theory. To derive the cross-price elasticities (which measure the extent of product substitution), we developed an economic model that describes consumers' consumption behavior under reasonable assumptions, and then used California cannabis data and some additional behavioral parameters from previous studies in our demand model. These demand (and supply) elasticities play critical roles in projecting demand response and in evaluating cannabis quantities, revenues and aggregate economic impacts.

8. Numerical Simulation of Changes in Cannabis Prices, Quantities, Revenues, and Taxes in Response to Changes in Proposed Regulations

8.1 Simulation parameters

The simulation model described above is characterized numerically by specifying values for the parameters listed. We begin by characterizing the initial situation without state or local cannabis taxation or regulation. The total legal-source cannabis (medicinal plus adult use) quantity share is 50% of total cannabis. The initial retail price is \$3,600 per pound of dried flower equivalent for the two legal sources. The price of illegal cannabis is about 65% of the medicinal price for a standard dried flower equivalent product. These relationships are described in previous chapters and are based on best available information.

Parameters are shown in Table 8.1. Some key parameter values assumed are the aggregate cannabis price elasticity equal to -0.2, as explained in Section 7.9. The budget share of aggregate cannabis consumption is calculated to be 0.03 based on annual expenditure of about \$200 per capita. The income elasticity for cannabis is assumed to be

1.0. Regular heavy users of cannabis have budget share as high as 5% or more, but broad industry information indicates that this group of users have low income elasticities of the quantity of cannabis consumed.

The substitution elasticity between medicinal and adult-use cannabis is 5.0; the substitution elasticity between medicinal and illegal cannabis is 2.0; and the substitution elasticity between adult-use and illegal cannabis is 2.0. The substitution matrix is symmetric. The conditional expenditure elasticities of each category are 1.0.

The underlying parameters and initial shares lead to the matrix of own- and cross-price elasticities of demand as shown, with large elasticities within the group. At initial shares, the own-price elasticities are -2.476 for medicinal, -2.252 for adult-use and -1.291 for illegal. These follow directly from the substitution elasticities, the group demand elasticity and the initial expenditure shares.

On the supply side, we assume a relatively elastic supply elasticity for each segment of cannabis (5.0). These apply to expected prices for a horizon of more than one season. Conditions and requirements for the medicinal and the adult-use segments are very similar and suppliers would find it easy to move between the two. We understand the track and trace system implies that immediate reallocation of cannabis between legal segments is not possible so the elastic supply applies with at least one growing season to adjust. These elasticities apply after any bottlenecks caused by regulations (for example testing capacity) are resolved and for a horizon over which constraints from track and trace are not binding. These high supply elasticities also imply that there is very little producer surplus after producers pay for the services of managers and the returns to capital, which reflect remaining risk premiums.

The supply elasticity of illegal cannabis sold in California is also 5.0, which assumes that these suppliers face small adjustments in adjusting the portion of their supply sold in California. In particular. Those suppliers remaining in the illegal market may have difficulty moving into legal production and supply because of operator human capital and

technical requirements related to production methods and management including detailed record keeping. It seems also difficult to shift an operation from legal to illegal given all the information about location and operator required for a license to operate legally. Operators that remain in the illegal segment may also be well suited to operating effectively in the illegal segment and earn higher returns there relative to other occupations open to them. Adjusting cannabis supply to be shipped out of California may also entail costs for suppliers that had specialized in the illegal segment within California and vice versa.

8.2 Shifts in demand and costs associated with adult-use legalization

With this set of parameters, including shares of the three segments, we considered the demand shifts associated with adult-use legalization and regulations other than Bureau regulations, as described in Chapters 5 through 7, to establish the Taxation Baseline quantities and prices.

We then considered some supply-side cost shifts also associated with adult-use legalization. The first shifts on the supply side are cost reductions for both legal segments caused by adult-use legalization, state licensing, and establishment of track-and-trace as described in Chapter 5. These cost reductions relate to reduced risk premiums and related costs from conducting illegal activities or dealing with suppliers and others engaged in illegal activities. For both the newly legal adult-use cannabis segment and the medicinal segment, the cost reduction is 10%. Even in the medicinal segment, retailers have often dealt with illegal or quasi-legal cultivation supply and distribution of raw materials even under the decriminalized environment for medicinal retailers. We assume that the continuing illegal segment will face higher costs by 10% because of increased enforcement and isolation from the legal segments, including the effects of enforced track-and-trace measures and some reporting of illegal activities by legal businesses. We have relatively little data to document these cost shifts, but they are consistent with the

broad magnitudes of current risk premiums estimated by the differences between market prices and measured accounting costs at both wholesale and retail.

The second supply-side cost shift we consider is the MAUCRSA-mandated state cultivation tax at the cultivator stage, which is \$148 per pound on a flower-equivalent basis, affecting raw material costs. The cultivation tax is assumed to be subsumed in the marginal cost shifts on a per-pound basis. Local taxes and regulations at the cultivation stage are \$128 per pound. State regulations at the cultivation stage are \$50 per pound.¹⁵⁸ State and local regulations and local taxes, including license fees, are \$95 at the manufacturing stage. In sum, these taxes and regulatory costs represent \$421 per pound for both the medicinal and the adult use segments. They represent an ad valorem equivalent cost shift of 15.8%, based on the initial sales-tax-inclusive price.

The third component is increased enforcement of the current sales tax and new introduced cannabis specific taxes. The sales tax is about 8.3% on cannabis for adult use cannabis and we assume an effective tax rate of 2.1% for medicinal because most of the cannabis sold in that segment will be exempt for the sales tax. The state tax rate is 7.25% and the average of county tax rates, which we assume is 1.05%, depends on how cannabis sales are distributed among local tax jurisdictions. Compliance in 2017 suggests about an effective 2.5% tax rate for medicinal cannabis. Local taxes are expected to be 7.8% for the medicinal segment and 8.2% for the adult-use segment. The new ad valorem excise tax is 15% on retail sales.

In the previous section, we derived the impact of such taxes on shifts on the cost side of the model. The net effect is higher costs for all segments. The equilibrium prices depend on the interactions of supply and demand in each segment and the solution for a new equilibrium.

¹⁵⁸ Although local testing taxes are technically imposed at the distribution level, not at the cultivation level, we include it in the first stage for simplicity.

Table 8.1 Initial prices and quantities and model parameters for simulations of the impacts of regulations

Cannabis group as a whole

| <i>Share of income spent on cannabis</i> | <i>Total quantity (1000s of lb)</i> | <i>Price/lb</i> | <i>Own demand elasticity</i> | <i>Income elasticity</i> |
|--|-------------------------------------|-----------------|------------------------------|--------------------------|
| 0.3% | 2,600 | \$2,970 | -0.2 | 1.0 |

| | <i>Quantity share</i> | <i>Price/lb</i> | <i>Elasticity of substitution between uses</i> | | <i>Conditional expenditure elasticity</i> |
|-----------|-----------------------|-----------------|--|-----|---|
| Medicinal | 23.1% | \$3,600 | Med and Adult | 5.0 | Medicinal |
| Adult-use | 26.9% | \$3,600 | Med and Illegal | 2.0 | Adult-use |
| Illegal | 50.0% | \$2,340 | Adult and Illegal | 2.0 | Illegal |

Implied demand elasticities matrix derived from basic parameters

Demand elasticities matrix derived from initial parameters

| | <i>Medicinal</i> | <i>Adult-use</i> | <i>Illegal</i> |
|-----------|------------------|------------------|----------------|
| Medicinal | -2.48 | 1.57 | 0.71 |
| Adult-use | 1.34 | -2.25 | 0.71 |
| Illegal | 0.50 | 0.59 | -1.29 |

| <i>Supply elasticities of medicinal cannabis regulations</i> | <i>Medicinal</i> | <i>Adult-use</i> | <i>Illegal</i> |
|--|------------------|------------------|----------------|
| | 5.0 | 5.0 | 5.0 |

8.3 Simulated results for the Taxation Baseline

We first establish the Taxation Baseline used to assess impacts of the proposed Bureau regulations and the two alternatives. As discussed in some detail above, this baseline corresponds to a hypothetical situation in which legalization, taxation, and other regulations are in place but the Bureau regulations are not. For comparisons we must establish prices, quantities, revenues and other industry economic variables for this baseline situation. We have used the detailed model of Chapter 7 and the assumptions explained in section 8.1 and 8.2 to establish this baseline. To make comparisons convenient, the baseline prices, quantities, revenues and taxes for medicinal, adult-use and illegal cannabis segments are provided in the first column in each of the tables in section 8.4.

8.4 Simulated regulation impacts on prices, quantities, and related variables

Results provided in Table 8.2a, 8.2b, 8.2c, 8.2d and 8.2e include the main results for the proposed Bureau regulations for the medicinal cannabis segment (8.2a), the adult-use segment (8.2b) the combined legal segments (8.2c) and the illegal cannabis segment (8.2d) and total cannabis (8.2e). The first column in each table shows the results for the Taxation Baseline to which the impacts of the Bureau regulations are compared. The second column shows the results under the proposed regulations. The third column shows the differences between the first two columns.

Each table has a series of rows that display prices, quantities, revenues, and details on taxes, including state and local taxes. In addition, prices and revenues are shown inclusive of and net of taxes, including excise taxes and all taxes.

In Chapter 6, we provided estimates of the costs of regulation per pound that apply to medicinal and adult-use cannabis after it leaves the cultivation and manufacturing stages. Overall, we find that the proposed Bureau regulations add approximately \$408 per pound of marketable dried flower equivalent in direct operating costs. The largest portion of

additional costs, \$257 per pound, is due to the added costs of required testing. Since legal adult-use cannabis regulations are expected to be similar to the regulations on medicinal cannabis, we also expect regulatory costs to be the same for the adult-use segment and the medicinal segment.

The second source of economic effects of regulations is an increase in consumer willingness to pay for legal cannabis that has more security, traceability, and intensive product testing. We assume the increase in willingness to pay per unit is equal to 6%. Such an increase in willingness to pay is consistent with data from food markets and other consumer goods. USDA certification in food markets such as eggs and meats and increased government-mandated testing, for example as introduced in pistachios all increase consumer willingness to pay for consumer goods (Gray et al. 2005). It is also consistent with improved traceability as modeled in Pouliot and Sumner (2008 and 2011) and the literature they cite. We also assume that when legal cannabis experiences an increased willingness to pay from added certifications and especially safety and security, the illegal segment experiences a negative willingness to pay also of 6%. Significant evidence from economic experiments and observations from newly regulated or expanded regulations of consumer goods support a positive impact, but the magnitude is less certain.

The prices, quantities, revenues, and taxes for the medicinal segment change in expected ways upon introducing the proposed regulations. Table 8.2a reports prices, quantities, revenues, and taxes for medicinal cannabis in the Taxation Baseline and with proposed Bureau regulations imposed. Here we focus on the column 3 which shows the economic effects of the proposed regulations on the medicinal cannabis segment by subtracting column 1 from column 2.

Price (including all taxes) rises by \$402 per pound, quantity rises by 21,380 pounds, and revenue rises by \$343 million (including taxes). The price net of excise taxes rises by \$354

and price net of taxes rises by \$322 per pound. Excise taxes add \$48 per pound and all taxes add \$80 per pound. Revenue after cannabis taxes rises by \$268 million.

Tax revenue rises by \$74 million, which is separated into a \$25 million increase for local taxes and a \$49 million increase for state taxes. Excise tax revenue rises by \$41 million.

The share of the medicinal cannabis segment, in terms of quantity, is approximately unchanged at 21.4% with regulations compared to total cannabis sold in California. The share of the medicinal cannabis segment in revenue increases by 1.1%.

The prices, quantities, revenues, and taxes for the adult-use segment also change in expected ways upon introducing the proposed regulations to the Taxation Baseline. Table 8.2b reports prices, quantities, revenues, and taxes for adult-use cannabis for the medicinal baseline and with proposed Bureau regulations imposed. The Taxation Baseline for the adult use segment is provided in column 1 for comparison. Here we again focus on the column 3 which shows the economic effects of the proposed regulations on the adult-use cannabis segment by subtracting column 1 from column 2.

The adult-use price shown in Table 8.2b (including all taxes) rises by \$406 per pound, quantity rises by 12,385 pounds, and revenue (including taxes) rises by \$352 million. The price net of the excise taxes rises by \$360 and price net of all taxes rises by \$310. The excise taxes add \$46 per pound and all taxes add \$97 per pound. Revenue after cannabis taxes rises by \$352 million. Tax revenue rises by \$87 million, which is separated into a \$26 million increase for local taxes and a \$61 million increase for state taxes. Excise tax revenue rises by \$40 million.

The share of the adult-use cannabis segment in terms of quantity falls slightly to 25.2% of cannabis sold in California, and the share of the adult-use cannabis segment in revenue net of taxes rises by 0.6%.

For convenience, Table 8.2c displays the average prices and the sum of quantities, revenues and taxes for the two legal segments. Legal cannabis share of quantity falls slightly to 46.6%, while revenue share rises 1.7% to 54.2% with the proposed regulations compared to the Taxation Baseline. Table 8.2d completes the picture by showing that with the proposed regulations, the illegal segment has a higher price by \$23 per pound, a higher quantity by about 62,000 pounds and a higher revenue by \$198 million to \$4,081 million. The illegal segment has a slight gain to 53.4% of total quantity sold and a slight loss to 45.8% of total revenue.

Tables 8.3a through 8.3e provide analogous information for the lower-cost regulations relative to the Taxation Baseline. The lower-cost regulations add approximately \$350 per pound in operating costs. Most of the addition to costs, \$235 per pound, is due to the added costs of testing. Again, legal adult-use cannabis regulations and medicinal cannabis regulations have the same costs in this alternative. The second source of economic effects of regulations is an increase in consumer willingness to pay for legal cannabis that has more security, traceability, and intensive product testing. We assume the increase in willingness to pay per unit is equal to 3% for both legal segments and -3% for the illegal segment. The reduced testing and lower security regulations cause consumers to be willing to pay less than under the proposed regulations.

The results in tables 8.3a through 8.3e may be briefly summarized. Overall, these lower-cost regulations cause prices to increase by less, cause quantities to increase by less and generally have smaller impacts than the proposed regulations. With the lower-cost regulations, legal quantity rises by 43,755 pounds and legal price averages \$344 per pound higher (Table 8.3c) compared to an average legal price increase of \$403 and a legal quantity increase of 33,765 pounds (Table 8.2c). The lower-cost regulations also imply less expansion of the illegal segment (28,029 pounds (Table 8.3d) compared to 62,061 pounds (Table 8.2d)).

Tables 8.4a through 8.4e provide the information for the higher-security regulations relative to the Taxation Baseline. The higher-security regulations add \$744 per pound in operating costs. Most of the addition to costs, \$414 per pound, is due to the added costs of testing. Again, legal adult-use cannabis regulations and medicinal cannabis regulations have the same costs in this alternative. We adjust willingness to pay for each segment by under this scenario by 3% up for the legal segments and down by 3% for the illegal segment.

The results in tables 8.4a through 8.4e may be briefly summarized. Overall, these higher-security regulations cause prices to increase by more and cause quantities to decline compared to impacts of the proposed regulations. With the higher-security regulations, legal quantity falls by 57,549 pounds and legal price averages \$724 per pound higher (Table 8.4c) compared to an average legal price increase of \$403 and a legal quantity increase of 33,765 pounds (Table 8.2c) under the proposed regulations.

Table 8.2a Impact of proposed Bureau regulations on the medicinal cannabis segment, given the Taxation Baseline

| Variables | Taxation Baseline | After Bureau regulations imposed on Baseline | Difference: After Bureau regulations imposed on Baseline |
|--|--------------------------|---|---|
| Price per lb, with tax | \$4,439 | \$4,841 | \$402 |
| Price per lb, without excise tax | \$3,906 | \$4,260 | \$354 |
| Price per lb, without total tax | \$3,278 | \$3,600 | \$322 |
| Excise tax rate per lb | \$533 | \$581 | \$48 |
| Total tax rate per lb | \$1,161 | \$1,241 | \$80 |
| Quantity (lbs) | 594,319 | 615,699 | 21,380 |
| Share of cannabis quantity | 21.4% | 21.4% | 0.0% |
| Revenue, with tax | \$2,638 million | \$2,981 million | \$343 million |
| Revenue, without tax | \$1,948 million | \$2,216 million | \$268 million |
| Total tax revenue | \$690 million | \$764 million | \$75 million |
| Local tax revenue | \$246 million | \$271 million | \$25 million |
| Excise tax revenue | \$317 million | \$358 million | \$41 million |
| Total state tax revenue | \$444 million | \$493 million | \$49 million |
| Share of cannabis revenue, without tax | 23.8% | 24.9% | 1.1% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.2b. Impact of proposed Bureau regulations on the adult-use cannabis segment, given the Taxation Baseline

| Variables | <i>Taxation Baseline</i> | <i>After Bureau regulations imposed on Baseline</i> | <i>Difference: After Bureau regulations imposed on Baseline</i> |
|--|--------------------------|---|---|
| Price per lb, with tax | \$4,698 | \$5,104 | \$406 |
| Price per lb, without excise tax | \$4,162 | \$4,522 | \$360 |
| Price per lb, without total tax | \$3,296 | \$3,606 | \$310 |
| Excise tax rate per lb | \$536 | \$582 | \$46 |
| Total tax rate per lb | \$1,401 | \$1,498 | \$97 |
| Quantity (lbs) | 711,264 | 723,649 | 12,385 |
| Share of cannabis quantity | 25.6% | 25.2% | -0.4% |
| Revenue, with tax | \$3,341 million | \$3,693 million | \$352 million |
| Revenue, without tax | \$2,345 million | \$2,609 million | \$265 million |
| Total tax revenue | \$997 million | \$1,084 million | \$87 million |
| Local tax revenue | \$326 million | \$352 million | \$26 million |
| Excise tax revenue | \$381 million | \$421 million | \$40 million |
| Total state tax revenue | \$671 million | \$732 million | \$61 million |
| Share of cannabis revenue, without tax | 28.7% | 29.3% | 0.6% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.2c. Impact of proposed Bureau regulations on combination of both legal cannabis segments, given the Taxation Baseline

| Variables | Taxation Baseline | After Bureau regulations imposed on Baseline | Difference: After Bureau regulations imposed on Baseline |
|--|--------------------------|---|---|
| Avg price per lb, with tax | \$4,580 | \$4,983 | \$403 |
| Avg price per lb, without tax | \$3,288 | \$3,616 | \$328 |
| Quantity (lbs) | 1,305,583 | 1,339,348 | 33,765 |
| Share of cannabis quantity | 47.0% | 46.6% | -0.4% |
| Revenue, with tax | \$5,979 million | \$6,674 million | \$695 million |
| Revenue, without tax | \$4,292 million | \$4,825 million | \$533 million |
| Total tax | \$1,687 million | \$1,849 million | \$162 million |
| Share of cannabis revenue, without tax | 52.5% | 54.2% | 1.7% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.2d. Impact of proposed Bureau regulations on illegal cannabis segment, given the Taxation Baseline

| Variables | <i>Taxation Baseline</i> | <i>After Bureau regulations imposed on Baseline</i> | <i>Difference: After Bureau regulations imposed on Baseline</i> |
|--|--------------------------|---|---|
| Price per lb | \$2,636 | \$2,659 | \$23 |
| Quantity (lbs) | 1,472,886 | 1,534,947 | 62,061 |
| Share of cannabis quantity | 53.0% | 53.4% | 0.4% |
| Revenue | \$3,883 million | \$4,081 million | \$198 million |
| Share of cannabis revenue, without tax | 47.5% | 45.8% | -1.7% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.2e. Impact of proposed Bureau regulations on all cannabis for sale in California, given the Taxation Baseline

| Variables | <i>Taxation Baseline</i> | <i>After Bureau regulations imposed on Baseline</i> | <i>Difference: After Bureau regulations imposed on Baseline</i> |
|----------------------|--------------------------|---|---|
| Quantity (lbs) | 2,778,469 | 2,874,295 | 95,826 |
| Revenue, without tax | \$8,176 million | \$8,906 million | \$730 million |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.3a. Impact of lower-cost Bureau regulations on the medicinal cannabis segment, given the Taxation Baseline

| Variables | Taxation Baseline | After Bureau regulations imposed on Baseline | Difference: After Bureau regulations imposed on Baseline |
|--|--------------------------|---|---|
| Price per lb, with tax | \$4,439 | \$4,782 | \$343 |
| Price per lb, without excise tax | \$3,906 | \$4,208 | \$302 |
| Price per lb, without total tax | \$3,278 | \$3,553 | \$275 |
| Excise tax rate per lb | \$533 | \$574 | \$41 |
| Total tax rate per lb | \$1,161 | \$1,229 | \$68 |
| Quantity (lbs) | 594,319 | 619,417 | 25,098 |
| Share of cannabis quantity | 21.4% | 21.7% | 0.3% |
| Revenue, with tax | \$2,638 million | \$2,962 million | \$324 million |
| Revenue, without tax | \$1,948 million | \$2,201 million | \$252 million |
| Total tax revenue | \$690 million | \$761 million | \$72 million |
| Local tax revenue | \$246 million | \$271 million | \$24 million |
| Excise tax revenue | \$317 million | \$356 million | \$39 million |
| Total state tax revenue | \$444 million | \$491 million | \$47 million |
| Share of cannabis revenue, without tax | 23.8% | 25.1% | 1.3% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.3b. Impact of lower-cost Bureau regulations on the adult-use cannabis segment, given the Taxation Baseline

| Variables | Taxation Baseline | After Bureau regulations imposed on Baseline | Difference: After Bureau regulations imposed on Baseline |
|--|--------------------------|---|---|
| Price per lb, with tax | \$4,698 | \$5,044 | \$347 |
| Price per lb, without excise tax | \$4,162 | \$4,469 | \$307 |
| Price per lb, without total tax | \$3,296 | \$3,560 | \$264 |
| Excise tax rate per lb | \$536 | \$575 | \$40 |
| Total tax rate per lb | \$1,401 | \$1,484 | \$83 |
| Quantity (lbs) | 711,264 | 729,921 | 18,657 |
| Share of cannabis quantity | 25.6% | 25.6% | 0.0% |
| Revenue, with tax | \$3,341 million | \$3,682 million | \$341 million |
| Revenue, without tax | \$2,345 million | \$2,599 million | \$254 million |
| Total tax revenue | \$997 million | \$1,083 million | \$87 million |
| Local tax revenue | \$326 million | \$352 million | \$26 million |
| Excise tax revenue | \$381 million | \$420 million | \$38 million |
| Total state tax revenue | \$671 million | \$731 million | \$60 million |
| Share of cannabis revenue, without tax | 28.7% | 29.6% | 0.9% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.3c. Impact of lower-cost Bureau regulations on combination of both legal cannabis segments, given the Taxation Baseline

| Variables | Taxation Baseline | After Bureau regulations imposed on Baseline | Difference: After Bureau regulations imposed on Baseline |
|--|--------------------------|---|---|
| Ave price per lb, with tax | \$4,580 | \$4,924 | \$344 |
| Ave price per lb, without tax | \$3,288 | \$3,557 | \$269 |
| Quantity (lbs) | 1,305,583 | 1,349,338 | 43,755 |
| Share of cannabis quantity | 47.0% | 47.3% | 0.3% |
| Revenue, with tax | \$5,979 million | \$6,644 million | \$665 million |
| Revenue, without tax | \$4,293 million | \$4,799 million | \$506 million |
| Total tax | \$1,687 million | \$1,845 million | \$158 million |
| Share of cannabis revenue, without tax | 52.5% | 54.7% | 2.2% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.3d. Impact of lower-cost Bureau regulations on illegal cannabis segment, given the Taxation Baseline

| Variables | <i>Taxation Baseline</i> | <i>After Bureau regulations imposed on Baseline</i> | <i>Difference: After Bureau regulations imposed on Baseline</i> |
|--|--------------------------|---|---|
| Price per lb | \$2,636 | \$2,646 | \$10 |
| Quantity (lbs) | 1,472,886 | 1,500,915 | 28,029 |
| Share of cannabis quantity | 53.0% | 52.7% | -0.3% |
| Revenue | \$3,883 million | \$3,972 million | \$89 million |
| Share of cannabis revenue, without tax | 47.5% | 45.3% | -2.2% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.3e. Impact of lower-cost Bureau regulations on all cannabis for sale in California, given the Taxation Baseline

| Variables | <i>Taxation Baseline</i> | <i>After Bureau regulations imposed on Baseline</i> | <i>Difference: After Bureau regulations imposed on Baseline</i> |
|----------------------|--------------------------|---|---|
| Quantity (lbs) | 2,778,469 | 2,850,253 | 71,784 |
| Revenue, without tax | \$8,176 million | \$8,771 million | \$595 million |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.4a. Impact of higher-security Bureau regulations on the medicinal cannabis segment, given the Taxation Baseline

| Variables | Taxation Baseline | After Bureau regulations imposed on Baseline | Difference: After Bureau regulations imposed on Baseline |
|--|--------------------------|---|---|
| Price per lb, with tax | \$4,439 | \$5,158 | \$719 |
| Price per lb, without excise tax | \$3,906 | \$4,539 | \$633 |
| Price per lb, without total tax | \$3,278 | \$3,854 | \$576 |
| Excise tax rate per lb | \$533 | \$619 | \$86 |
| Total tax rate per lb | \$1,161 | \$1,304 | \$143 |
| Quantity (lbs) | 594,319 | 576,420 | -17,899 |
| Share of cannabis quantity | 21.4% | 20.0% | -1.4% |
| Revenue, with tax | \$2,638 million | \$2,973 million | \$335 million |
| Revenue, without tax | \$1,948 million | \$2,221 million | \$273 million |
| Total tax revenue | \$690 million | \$752 million | \$62 million |
| Local tax revenue | \$246 million | \$266 million | \$19 million |
| Excise tax revenue | \$317 million | \$357 million | \$40 million |
| Total state tax revenue | \$444 million | \$486 million | \$43 million |
| Share of cannabis revenue, without tax | 23.8% | 24.1% | +0.3% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.4b. Impact of higher-security Bureau regulations on the adult-use cannabis segment, given the Taxation Baseline

| Variables | Taxation Baseline | After Bureau regulations imposed on Baseline | Difference: After Bureau regulations imposed on Baseline |
|--|--------------------------|---|---|
| Price per lb, with tax | \$4,698 | \$5,429 | \$732 |
| Price per lb, without excise tax | \$4,162 | \$4,810 | \$648 |
| Price per lb, without total tax | \$3,296 | \$3,853 | \$557 |
| Excise tax rate per lb | \$536 | \$619 | \$83 |
| Total tax rate per lb | \$1,401 | \$1,577 | \$175 |
| Quantity (lbs) | 711,264 | 671,614 | -39,650 |
| Share of cannabis quantity | 25.6% | 23.2% | -2.4% |
| Revenue, with tax | \$3,341 million | \$3,646 million | \$305 million |
| Revenue, without tax | \$2,345 million | \$2,587 million | \$243 million |
| Total tax revenue | \$997 million | \$1,058 million | \$62 million |
| Local tax revenue | \$326 million | \$342 million | \$16 million |
| Excise tax revenue | \$381 million | \$416 million | \$35 million |
| Total state tax revenue | \$671 million | \$716 million | \$46 million |
| Share of cannabis revenue, without tax | 28.7% | 28.1% | -0.6% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.4c. Impact of higher-security Bureau regulations on combination of both legal cannabis segments, given the Taxation Baseline

| Variables | Taxation Baseline | After Bureau regulations imposed on Baseline | Difference: After Bureau regulations imposed on Baseline |
|--|--------------------------|---|---|
| Ave price per lb, with tax | \$4,580 | \$5,304 | \$724 |
| Ave price per lb, without tax | \$3,288 | \$3,853 | \$565 |
| Quantity (lbs) | 1,305,583 | 1,248,035 | -57,549 |
| Share of cannabis quantity | 47.0% | 43.3% | -3.7% |
| Revenue, with tax | \$5,979 million | \$6,620 million | \$641 million |
| Revenue, without tax | \$4,293 million | \$4,809 million | \$516 million |
| Total tax | \$1,687 million | \$1,811 million | \$124 million |
| Share of cannabis revenue, without tax | 52.5% | 52.2% | -0.3% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.4d. Impact of higher-security Bureau regulations on illegal cannabis segment, given the Taxation Baseline

| Variables | <i>Taxation Baseline</i> | <i>After Bureau regulations imposed on Baseline</i> | <i>Difference: After Bureau regulations imposed on Baseline</i> |
|--|--------------------------|---|---|
| Price per lb | \$2,636 | \$2,695 | \$59 |
| Quantity (lbs) | 1,472,886 | 1,635,660 | 162,774 |
| Share of cannabis quantity | 53.0% | 56.7% | 3.7% |
| Revenue | \$3,883 million | \$4,408 million | \$525 million |
| Share of cannabis revenue, without tax | 47.5% | 47.8% | 0.3% |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

Table 8.4e. Impact of higher-security Bureau regulations on all cannabis for sale in California, given the Taxation Baseline

| Variables | <i>Taxation Baseline</i> | <i>After Bureau regulations imposed on Baseline</i> | <i>Difference: After Bureau regulations imposed on Baseline</i> |
|----------------------|--------------------------|---|---|
| Quantity (lbs) | 2,778,469 | 2,883,695 | 105,226 |
| Revenue, without tax | \$8,176 million | \$9,217 million | \$1,041 million |

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

Note: For details on the proposed package of regulations, see Chapter 6.

9. Economy-wide impacts of regulations in the medicinal and adult-use cannabis segments

This chapter reports on the impacts of the proposed regulations on the broader economy, especially those parts of the economy not directly within the cannabis industry. The impact estimates build directly on the results presented in Table 8.2a and 8.2b and the analogous tables for the lower-cost and higher-security alternatives. The tables presented in this chapter describe how changes in medicinal and adult-use cannabis segments ripple through the economy. We use a modified version of the IMPLAN input/output model and data set to develop the economy-wide impacts. For readers unfamiliar with this approach a brief discussion of IMPLAN and similar models is provided as background in Chapter 13.

The IMPLAN version 2014 data set was adjusted to incorporate information about medicinal cannabis, which is not a separate covered industry in the IMPLAN data set. In particular, we adjusted the ratio of value added to intermediate purchases and the shares within value added to reflect tax payments among other modifications. The IMPLAN analysis was conducted using three sectors in cannabis. These are treated as “industries” in the IMPLAN nomenclature.

The three sectors correspond to the three sets of services that are the subject of proposed regulations. These are distribution (wholesale functions), testing and retailing. Farm cultivation and manufacturing of medicinal and adult-use cannabis are not a part of this analysis. We note that for wholesale and retail industries the IMPLAN framework treats “output” (in dollar value terms) as the difference between gross sales revenues collected by the wholesale or retail business sector minus the dollar value of the costs of goods sold by the wholesale or retail business sector. Therefore, IMPLAN analysis of wholesale and retail businesses does not include backward linkages from the wholesale (distribution) industry back to the raw and manufactured materials that represent costs of goods sold for distributors. Similarly, the IMPLAN linkages analyzed for the retail industry do not include the cost of goods that are acquired from the distributors. This means there

is no double counting when we include both distribution businesses and retailers in the IMPLAN modeling.

For retailing, we considered IMPLAN industry number 401 (drug stores and related retailers) as the best match from which to make adjustments. For distribution, we considered IMPLAN industry number 395 (wholesalers) as the best match from which to make adjustments. For testing, we considered IMPLAN industry number 479 (medicinal and diagnostic laboratories) as the best match from which to make adjustments.

We do not attempt to draw economy-wide implications of regulations of medicinal and adult-use cannabis for the illegal segment of California cannabis. While this segment is affected by the proposed regulations, it is beyond the scope of this report to analyze those implications in an economy-wide context. Table 8.2d considers how proposed regulations affect illegal cannabis directly. However, data are not available to develop economy-wide linkages for the illegal segment.

9.1 Multipliers

Table 9.1 provides the detailed multipliers for the three “industries” that compose the portions of the legal cannabis segments that will be licensed and overseen by the Bureau, from its wholesale transfer from cultivator to distributor or retailer to its retail transfer to the consumer. These multipliers are used to calculate impacts of the “value of output” of the industry changes. In each case, multipliers are presented as dollars per dollar of output. Recall that for distribution and dispensing, “value of output” is defined as sales revenue minus costs of goods sold. Thus, for example, the value of the output of the retailer is its revenue minus the cost they paid for the products that it sells. Retailer output is valued by the provision of retail services, not by gross sales revenue. Testing output is the value of services provided, which is the revenue of the sector.

Value added is defined as the contribution to gross state product of the sector (output minus the value of indirect inputs purchased from other sectors). For example, for a

retailer, these indirect input purchases include normal retail-level purchases such as display labels, electricity services, cleaning supplies, costs of equipment such as fans or added lights, and cash registers. Labor income associated with the business is a part of value added and includes proprietor income as well as hired employee wages and salaries. Value added includes business taxes and other returns to the operation.

The final panel of Table 9.1 includes jobs per million dollars of output. This is calculated as the number of employees and managers employed in the industry divided by total value of output as defined above for each industry sector. For each industry sector, the multipliers are provided for indirect effects. These multipliers represent the ripple effects of purchases by the medicinal cannabis industry from other industries outside the medicinal cannabis segment. First-level purchases and subsequent ripples are both considered. This effect is described more fully in Section 13.

The induced effects are the ripples associated with purchases made by those that earn the value added of the industry. So, for example, employee wages are spent on goods and services from other industries ripple through the economy creating additional value added, labor income and employment. The total effect adds the direct effect to indirect and induced effects.

Table 9.1. Statewide impact multipliers for cannabis sectors of distribution, testing and retailing

| Impact Measure | Distribution | Testing | Retailing |
|-------------------------------|---|----------------|------------------|
| Value of Sector Output | Output for economy per 1.00 output by cannabis sector (USD) | | |
| Direct Output | 1 | 1 | 1 |
| Indirect Output | 0.402 | 0.703 | 0.285 |
| Induced Output | 0.569 | 0.547 | 0.470 |
| Total Output | 1.971 | 2.250 | 1.756 |
| Value Added | GDP per 1.00 of output (USD) | | |
| Direct Value Added | 0.681 | 0.345 | 0.778 |
| Indirect Value Added | 0.249 | 1.263 | 0.179 |
| Induced Value Added | 0.340 | 0.946 | 0.281 |
| Total Value Added | 1.269 | 3.209 | 1.238 |
| Labor Income | Labor income per 1.00 output by sector (USD) | | |
| Direct Labor Income | 0.475 | 0.332 | 0.426 |
| Indirect Labor Income | 0.164 | 0.844 | 0.104 |
| Induced Labor Income | 0.197 | 0.570 | 0.163 |
| Total Labor Income | 0.837 | 2.414 | 0.693 |
| Employment | Jobs per 1 million USD of output | | |
| Direct Employment | 4.80 | 3.25 | 10.50 |
| Indirect Employment | 2.40 | 4.00 | 1.60 |
| Induced Employment | 3.60 | 3.40 | 3.00 |
| Total Employment | 10.80 | 10.60 | 15.10 |

Source: Multipliers were generated in IMPLAN using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

9.2 Economy-wide contributions under the Taxation Baseline

We present two baseline tables for economy-wide results here. These tables are solely used to estimate the differences with the regulation scenarios presented in the next section.

Table 9.2a builds off the results presented in column 1 of Table 8.2a. The top row of Table 9.2 lists the direct value of output related to medicinal cannabis expected under the Taxation Baseline without proposed Bureau regulations. In this case, IMPLAN shows output of \$103.8 million for distribution, minimal output of \$1.3 million for testing and output of about \$1,474.2 million for dispensing. We note that these outputs include taxes. Recall that taxes are a significant share of revenue for the retailers. Labor income is more than half of the value of output for retailers. Recall that this includes returns to proprietors. The reason it is not a higher share is because taxes are such a large share of value added.

All the rest of the rows of Table 9.2a are derived from the top row using the multipliers in Table 9.1a. These show value added, labor income and direct jobs as well as Baseline indirect and induced ripple effects and totals. For example, in the Baseline, there are 498 direct jobs and 1,121 total jobs associated with the distribution sector for medicinal cannabis. Likewise, there are 15,479 direct jobs and 22,260 jobs in total associated with retailing medical cannabis.

Table 9.2b provides the Taxation Baseline economy-wide estimates for the adult-use segment. It builds off the results presented in column 1 of Table 8.2b. The top row of Table 9.2b lists the direct value of output related to adult-use cannabis expected under the Baseline without proposed Bureau regulations. In this case, IMPLAN shows output of \$120.2 million for distribution, minimal output of \$1.6 million for testing and output of \$1,952.3 million for retailing. All the rest of the rows of Table 9.2b are derived from the top row using the multipliers in Table 9.1. These show value added, labor income and direct jobs as well as Taxation Baseline indirect and induced ripple effects and totals. For

example, in the Baseline, there are 577 direct jobs and 1,298 total jobs associated with the distribution of adult-use cannabis. Likewise, there are 20,499 direct jobs and 29,479 total jobs associate with retailing.

Table 9.2a. Economic contributions of the medicinal cannabis segment, given the Taxation Baseline: without proposed Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|-------------------------------|-----------------------|-------------------------|
| Value of Sector Output | <i>Millions of USD</i> | | |
| Direct Output | 103.8 | 1.3 | 1,474.2 |
| Indirect Output | 41.7 | 0.9 | 420.1 |
| Induced Output | 59.0 | 0.7 | 692.9 |
| Total Output | 204.5 | 3.0 | 2,588.6 |
| Value Added | | | |
| Direct Value Added | 70.7 | 0.5 | 1,146.9 |
| Indirect Value Added | 25.8 | 1.7 | 263.9 |
| Induced Value Added | 35.3 | 1.2 | 414.2 |
| Total Value Added | 131.7 | 4.2 | 1,825.0 |
| Labor Income | | | |
| Direct Labor Income | 49.3 | 0.4 | 628.0 |
| Indirect Labor Income | 17.0 | 1.1 | 153.3 |
| Induced Labor Income | 20.4 | 0.7 | 240.3 |
| Total Labor Income | 86.9 | 3.2 | 1,021.6 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | <i>Number of Jobs</i> | | |
| Direct Employment | 498 | 4 | 15,479 |
| Indirect Employment | 249 | 5 | 2,359 |
| Induced Employment | 374 | 4 | 4,422 |
| Total Employment | 1,121 | 14 | 22,260 |

Source: Values were estimated by AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.2b. Economic contributions of the adult-use cannabis segment, given the Taxation Baseline: without proposed Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|------------------------|-------------------------|
| Value of Sector Output | | <u>Millions of USD</u> | |
| Direct Output | 120.2 | 1.6 | 1,952.3 |
| Indirect Output | 48.3 | 1.1 | 556.4 |
| Induced Output | 68.4 | 0.9 | 917.6 |
| Total Output | 236.9 | 3.5 | 3,428.2 |
| Value Added | | | |
| Direct Value Added | 81.8 | 0.5 | 1,518.9 |
| Indirect Value Added | 29.9 | 2.0 | 349.5 |
| Induced Value Added | 40.9 | 1.5 | 548.6 |
| Total Value Added | 152.5 | 5.0 | 2,416.9 |
| Labor Income | | | |
| Direct Labor Income | 57.1 | 0.5 | 831.7 |
| Indirect Labor Income | 19.7 | 1.3 | 203.0 |
| Induced Labor Income | 23.7 | 0.9 | 318.2 |
| Total Labor Income | 100.6 | 3.8 | 1,352.9 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | | <u>Number of Jobs</u> | |
| Direct Employment | 577 | 5 | 20,499 |
| Indirect Employment | 288 | 6 | 3,124 |
| Induced Employment | 433 | 5 | 5,857 |
| Total Employment | 1,298 | 17 | 29,479 |

Source: Values were estimated by AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

9.3 Economy-wide contributions under the proposed regulations

This section presents economy-wide results for medicinal and adult-use cannabis under the proposed regulations, focusing on comparing these results with the Taxation Baseline.

Table 9.3a builds on the results presented in column 2 of Table 8.2a. The top row of Table 9.3a is the direct value of output. Output is \$142.8 million for distribution and \$35.3 million for testing. Recall that testing becomes mandatory and costs are about \$257 per pound with the proposed regulations. Output is about \$1,581.3 million for dispensing. Much of the increase of the value of output is due to costs of regulations that add to costs at retail. Recall that taxes are about 26% of revenue for the retailers, and that these taxes apply to the higher market prices caused by regulations. Further, recall that because consumer willingness to pay rises with more security and safety, the quantity sold rises.

With the proposed regulations, 16,603 direct jobs are in the retailing of medical cannabis, and these contribute 23,877 jobs to the economy overall. The testing sector contributes 115 direct jobs and 374 jobs to the economy overall. Distribution has 685 direct jobs and total employment impact is 1,542 jobs.

Table 9.3b shows the economic impact of the proposed regulations for the medical segment compared to the Taxation Baseline. Each entry in Table 9.3b is the difference between the entry in Table 9.3a and the associated number in the Baseline reported in Table 9.2a. Table 9.3b shows that the proposed regulations expand the economic activity in all sectors of the medicinal cannabis segment. In particular, the large increases associated with mandatory testing are evident. Consider an example to see how the entries in Table 9.3b are derived. Direct output in retailing is \$1,581.3 million from Table 9.3a. The analogous number in Table 9.2a is 1,474.2 million. The difference is \$107.1 million, which is the gain in direct output of retailing medicinal cannabis in Table 9.3b. A review of Table 9.3b shows substantial gains in economic activity in testing, retailing, and overall.

Table 9.3c builds on the results presented in column 2 of Table 8.2b for the adult-use segment. The top row of Table 9.3c is the direct value of output. Output is 157.8 million for distribution and 41.5 million for testing. Output is about \$2,058.9 million for retailing. With regulation, 21,618 direct jobs are in the retail sector, and these contribute 31,089 jobs to the economy overall. The testing sector contributes 135 direct jobs and 440 jobs to the economy overall. Distribution has 757 direct jobs and total employment impacts are 1,704 jobs.

Table 9.3d is identical in interpretation as Table 9.3b, but for the adult-use cannabis segment. Table 9.3d shows the economic impact of the proposed regulations for the adult-use segment compared to the Taxation Baseline. Each entry in Table 9.3d is the difference between the entry in Table 9.3c and the associated number in the Baseline reported in Table 9.2b. Table 9.3d shows that the proposed regulations expand the economic activity in the adult-use cannabis segment other than very small reduction in distribution. Again, there are large increases associated with mandatory testing. An example is instructive to see how the entries in Table 9.3d are derived from Table 9.3c and 9.2b. Direct output in retailing is \$2,058.9 million from Table 9.3c. The analogous number in Table 9.2b is \$1,952.3 million. The difference is \$106.6 million, which is the gain in direct output of the retail part of the medicinal segment shown in Table 9.3d. A review of adult-use regulation in Table 9.3d shows substantial gains in economic activity in testing and retailing and slight gains in distribution.

The overall economy-wide impacts for the proposed regulations compared to the Taxation Baseline are shown in Table 9.3e. Table 9.3e includes the sum of impacts for medicinal and adult-use segments. Each entry in Table 9.3e is simply the sum of the entries in Table 9.3b and Table 9.3d, which are themselves differences from the Taxation Baselines. Table 9.3e shows that the proposed regulations for legal cannabis expand economic activity substantially compared to the Taxation Baseline. There are large economic gains associated with mandatory testing and with dispensing. A review of Table 9.3e shows substantial gains in economic activity in testing, retailing, and overall.

Table 9.3a. Economic contributions of the medicinal cannabis segment, given the Taxation Baseline plus proposed Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|------------------------|-------------------------|
| Value of Sector Output | | <u>Millions of USD</u> | |
| Direct Output | 142.8 | 35.3 | 1,581.3 |
| Indirect Output | 57.4 | 24.8 | 450.7 |
| Induced Output | 81.2 | 19.3 | 743.2 |
| Total Output | 281.4 | 79.4 | 2,776.7 |
| Value Added | | | |
| Direct Value Added | 97.2 | 12.2 | 1,230.2 |
| Indirect Value Added | 35.5 | 44.6 | 283.0 |
| Induced Value Added | 48.5 | 33.4 | 444.3 |
| Total Value Added | 181.2 | 113.2 | 1,957.6 |
| Labor Income | | | |
| Direct Labor Income | 67.8 | 11.7 | 673.6 |
| Indirect Labor Income | 23.4 | 29.8 | 164.5 |
| Induced Labor Income | 28.1 | 20.1 | 257.7 |
| Total Labor Income | 119.5 | 85.2 | 1,095.8 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | | <u>Number of Jobs</u> | |
| Direct Employment | 685 | 115 | 16,603 |
| Indirect Employment | 343 | 141 | 2,530 |
| Induced Employment | 514 | 120 | 4,744 |
| Total Employment | 1,542 | 374 | 23,877 |

Source: Values were estimated by AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.3b. Differences in economic contributions of the medicinal cannabis segment between the Taxation Baseline and the Baseline plus proposed Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|-------------------------------|-----------------------|-------------------------|
| Value of Sector Output | <i>Millions of USD</i> | | |
| Direct Output | 39.0 | 34.0 | 107.1 |
| Indirect Output | 15.7 | 23.9 | 30.5 |
| Induced Output | 22.2 | 18.6 | 50.3 |
| Total Output | 76.9 | 76.4 | 188.1 |
| Value Added | | | |
| Direct Value Added | 26.6 | 11.7 | 83.3 |
| Indirect Value Added | 9.7 | 42.9 | 19.2 |
| Induced Value Added | 13.3 | 32.1 | 30.1 |
| Total Value Added | 49.5 | 109.0 | 132.6 |
| Labor Income | | | |
| Direct Labor Income | 18.5 | 11.3 | 45.6 |
| Indirect Labor Income | 6.4 | 28.7 | 11.1 |
| Induced Labor Income | 7.7 | 19.4 | 17.5 |
| Total Labor Income | 32.6 | 82.0 | 74.2 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | <i>Number of Jobs</i> | | |
| Direct Employment | 187 | 111 | 1,125 |
| Indirect Employment | 94 | 136 | 171 |
| Induced Employment | 140 | 116 | 321 |
| Total Employment | 421 | 360 | 1,617 |

Source: Values were estimated by AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.3c. Economic contributions of the adult-use cannabis segment, given the Taxation Baseline plus proposed Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|-------------------------------|-----------------------|-------------------------|
| Value of Sector Output | <i>Millions of USD</i> | | |
| Direct Output | 157.8 | 41.5 | 2,058.9 |
| Indirect Output | 63.4 | 29.1 | 586.8 |
| Induced Output | 89.8 | 22.7 | 967.7 |
| Total Output | 311.0 | 93.3 | 3,615.3 |
| Value Added | | | |
| Direct Value Added | 107.5 | 14.3 | 1,601.8 |
| Indirect Value Added | 39.3 | 52.4 | 368.5 |
| Induced Value Added | 53.6 | 39.2 | 578.5 |
| Total Value Added | 200.2 | 133.1 | 2,548.9 |
| Labor Income | | | |
| Direct Labor Income | 75.0 | 13.8 | 877.1 |
| Indirect Labor Income | 25.9 | 35.0 | 214.1 |
| Induced Labor Income | 31.1 | 23.6 | 335.6 |
| Total Labor Income | 132.1 | 100.1 | 1,426.8 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | <i>Number of Jobs</i> | | |
| Direct Employment | 757 | 135 | 21,618 |
| Indirect Employment | 379 | 166 | 3,294 |
| Induced Employment | 568 | 141 | 6,177 |
| Total Employment | 1,704 | 440 | 31,089 |

Source: Values were estimated by AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.3d. Differences in economic contributions of the adult-use cannabis segment between the Taxation Baseline and the Baseline plus proposed Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|------------------------|-------------------------|
| Value of Sector Output | | <u>Millions of USD</u> | |
| Direct Output | 37.6 | 39.9 | 106.6 |
| Indirect Output | 15.1 | 28.0 | 30.4 |
| Induced Output | 21.4 | 21.8 | 50.1 |
| Total Output | 74.1 | 89.8 | 187.1 |
| Value Added | | | |
| Direct Value Added | 25.6 | 13.8 | 82.9 |
| Indirect Value Added | 9.4 | 50.4 | 19.1 |
| Induced Value Added | 12.8 | 37.7 | 29.9 |
| Total Value Added | 47.7 | 128.0 | 131.9 |
| Labor Income | | | |
| Direct Labor Income | 17.9 | 13.2 | 45.4 |
| Indirect Labor Income | 6.2 | 33.7 | 11.1 |
| Induced Labor Income | 7.4 | 22.7 | 17.4 |
| Total Labor Income | 31.5 | 96.3 | 73.9 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | | <u>Number of Jobs</u> | |
| Direct Employment | 180 | 130 | 1,119 |
| Indirect Employment | 90 | 160 | 171 |
| Induced Employment | 135 | 136 | 320 |
| Total Employment | 406 | 423 | 1,609 |

Source: Values were estimated by AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.3e. Combined differences in economic contributions of the medicinal and adult-use cannabis segments between the Taxation Baseline and the Baseline plus proposed Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|----------------------------|-------------------------|
| Value of Sector Output | | <u>Millions of USD</u> | |
| Direct Output | 76.6 | 73.9 | 213.7 |
| Indirect Output | 30.8 | 51.9 | 60.9 |
| Induced Output | 43.6 | 40.4 | 100.4 |
| Total Output | 151.0 | 166.2 | 375.2 |
| Value Added | | | |
| Direct Value Added | 52.2 | 25.5 | 166.2 |
| Indirect Value Added | 19.1 | 93.3 | 38.2 |
| Induced Value Added | 26.0 | 69.9 | 60.0 |
| Total Value Added | 97.2 | 237.1 | 264.5 |
| Labor Income | | | |
| Direct Labor Income | 36.4 | 24.5 | 91.0 |
| Indirect Labor Income | 12.6 | 62.4 | 22.2 |
| Induced Labor Income | 15.1 | 42.1 | 34.8 |
| Total Labor Income | 64.1 | 178.3 | 148.1 |
| <i>Impact Measure</i> | | <i>Distribution</i> | <i>Testing</i> |
| Employment | | <u>Number of Jobs</u> | |
| Direct Employment | 368 | 240 | 2,244 |
| Indirect Employment | 184 | 295 | 342 |
| Induced Employment | 276 | 251 | 641 |
| Total Employment | 827 | 783 | 3,227 |

Source: Values were estimated by AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

9.4 Economy-wide contributions under the alternative regulations

This section provides six tables to summarize the economy-wide economic impact of the alternative regulations for medicinal and adult-use cannabis segments compared to the Taxation Baseline scenarios presented in Table 9.2a (for the medicinal segment) and Table 9.2b (for the adult-use segment). All six tables are presented as differences from the Baseline and are thus analogous to Tables 9.3b, 9.3d and 9.3e.

Table 9.4a presents differences from the lower-cost alternative regulations for the medicinal cannabis segment compared to the Taxation Baseline for the medicinal cannabis segment. There are gains, especially related to testing, but they are smaller than for the proposed regulations. Table 9.4b presents differences from the lower-cost alternative regulations for the adult-use cannabis segment compared to the appropriate Baseline in Table 9.2b. Again, there are gains testing and retailing but negative economic activity for distribution in this case. Table 9.4c presents combined differences from the lower-cost alternative regulations compared to the Baseline. Overall, there are gains from testing and retailing, but as expected negative impact on economic activity related to distribution.

Table 9.5a presents differences from the higher-security alternative regulations for the medicinal cannabis segment compared to the Taxation Baseline for the medicinal cannabis segment. There are gains related to testing and retail. But there are also significant economic losses compared to the Baseline for distribution. Table 9.5b presents differences from the high-security alternative regulations for the adult-use cannabis segment compared to the appropriate Baseline in Table 9.2b. Again, there are gains from testing and retailing but negative economic activity for distribution. Finally, Table 9.5c presents combined differences from the higher-security alternative regulations compared to the Baseline. Again, there are gains from testing and retailing, but as expected negative impact on economic activity related to distribution that limit the overall economic gains in employment or other measures.

Table 9.4a. Differences in economic contributions of the medicinal cannabis segment, between the Taxation Baseline and proposed lower-cost Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|------------------------|-------------------------|
| Value of Sector Output | | <u>Millions of USD</u> | |
| Direct Output | -21.1 | 20.5 | 155.2 |
| Indirect Output | -8.5 | 14.4 | 44.2 |
| Induced Output | -12.0 | 11.2 | 72.9 |
| Total Output | -41.5 | 46.2 | 272.5 |
| Value Added | | | |
| Direct Value Added | -14.3 | 7.1 | 120.7 |
| Indirect Value Added | -5.2 | 25.9 | 27.8 |
| Induced Value Added | -7.2 | 19.4 | 43.6 |
| Total Value Added | -26.7 | 65.9 | 192.1 |
| Labor Income | | | |
| Direct Labor Income | -10.0 | 6.8 | 66.1 |
| Indirect Labor Income | -3.5 | 17.3 | 16.1 |
| Induced Labor Income | -4.1 | 11.7 | 25.3 |
| Total Labor Income | -17.6 | 49.6 | 107.5 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | | <u>Number of Jobs</u> | |
| Direct Employment | -101 | 67 | 1,629 |
| Indirect Employment | -51 | 82 | 248 |
| Induced Employment | -76 | 70 | 466 |
| Total Employment | -227 | 218 | 2,343 |

Source: Values were estimated by AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.4b. Differences in economic contributions of the adult-use cannabis segment, between the Taxation Baseline and proposed lower-cost Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|-------------------------------|-----------------------|-------------------------|
| Value of Sector Output | <i>Millions of USD</i> | | |
| Direct Output | -35.9 | 24.2 | 172.5 |
| Indirect Output | -14.4 | 17.0 | 49.2 |
| Induced Output | -20.4 | 13.2 | 81.1 |
| Total Output | -70.7 | 54.4 | 302.9 |
| Value Added | | | |
| Direct Value Added | -24.4 | 8.3 | 134.2 |
| Indirect Value Added | -8.9 | 30.5 | 30.9 |
| Induced Value Added | -12.2 | 22.9 | 48.5 |
| Total Value Added | -45.5 | 77.6 | 213.6 |
| Labor Income | | | |
| Direct Labor Income | -17.0 | 8.0 | 73.5 |
| Indirect Labor Income | -5.9 | 20.4 | 17.9 |
| Induced Labor Income | -7.1 | 13.8 | 28.1 |
| Total Labor Income | -30.0 | 58.4 | 119.6 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | <i>Number of Jobs</i> | | |
| Direct Employment | -172 | 79 | 1,811 |
| Indirect Employment | -86 | 97 | 276 |
| Induced Employment | -129 | 82 | 518 |
| Total Employment | -387 | 256 | 2,605 |

Source: Values were estimated by UC AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.4c. Combined differences in economic contributions of the medicinal and adult-use cannabis segment between the Taxation Baseline plus proposed lower-cost Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|------------------------|-------------------------|
| Value of Sector Output | | <u>Millions of USD</u> | |
| Direct Output | -56.9 | 44.7 | 327.7 |
| Indirect Output | -22.9 | 31.4 | 93.4 |
| Induced Output | -32.4 | 24.5 | 154.0 |
| Total Output | -112.2 | 100.6 | 575.5 |
| Value Added | | | |
| Direct Value Added | -38.8 | 15.4 | 255.0 |
| Indirect Value Added | -14.2 | 56.5 | 58.7 |
| Induced Value Added | -19.4 | 42.3 | 92.1 |
| Total Value Added | -72.3 | 143.5 | 405.7 |
| Labor Income | | | |
| Direct Labor Income | -27.0 | 14.8 | 139.6 |
| Indirect Labor Income | -9.3 | 37.8 | 34.1 |
| Induced Labor Income | -11.2 | 25.5 | 53.4 |
| Total Labor Income | -47.7 | 108.0 | 227.1 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | | <u>Number of Jobs</u> | |
| Direct Employment | -273 | 145 | 3,441 |
| Indirect Employment | -137 | 179 | 524 |
| Induced Employment | -205 | 152 | 983 |
| Total Employment | -615 | 474 | 4,948 |

Source: Values were estimated by UC AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.5a. Differences in economic contributions of the medicinal cannabis segment between the Taxation Baseline and proposed higher-security Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|-------------------------------|-------------------------|
| Value of Sector Output | | <i>Millions of USD</i> | |
| Direct Output | -74.6 | 122.5 | 203.1 |
| Indirect Output | -30.0 | 86.1 | 57.9 |
| Induced Output | -42.4 | 67.0 | 95.5 |
| Total Output | -147.0 | 275.7 | 356.7 |
| Value Added | | | |
| Direct Value Added | -50.8 | 42.3 | 158.0 |
| Indirect Value Added | -18.6 | 154.8 | 36.4 |
| Induced Value Added | -25.4 | 115.9 | 57.1 |
| Total Value Added | -94.6 | 393.3 | 251.5 |
| Labor Income | | | |
| Direct Labor Income | -35.4 | 40.7 | 86.5 |
| Indirect Labor Income | -12.2 | 103.5 | 21.1 |
| Induced Labor Income | -14.7 | 69.8 | 33.1 |
| Total Labor Income | -62.4 | 295.9 | 140.8 |
| <i>Impact Measure</i> | | <i>Distribution</i> | <i>Testing</i> |
| Employment | | <i>Number of Jobs</i> | |
| Direct Employment | -358 | 399 | 2,133 |
| Indirect Employment | -179 | 490 | 325 |
| Induced Employment | -268 | 417 | 609 |
| Total Employment | -805 | 1,299 | 3,067 |

Source: Values were estimated by UC AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.5b. Differences in the economic contributions of the adult-use cannabis segments, between the Taxation Baseline and proposed higher-security Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|----------------------------|-------------------------|
| Value of Sector Output | | <u>Millions of USD</u> | |
| Direct Output | -105.1 | 142.7 | 203.2 |
| Indirect Output | -42.2 | 100.3 | 57.9 |
| Induced Output | -59.8 | 78.1 | 95.5 |
| Total Output | -207.1 | 321.1 | 356.7 |
| Value Added | | | |
| Direct Value Added | -71.5 | 49.2 | 158.1 |
| Indirect Value Added | -26.2 | 180.3 | 36.4 |
| Induced Value Added | -35.7 | 135.0 | 57.1 |
| Total Value Added | -133.3 | 458.1 | 251.5 |
| Labor Income | | | |
| Direct Labor Income | -49.9 | 47.4 | 86.5 |
| Indirect Labor Income | -17.2 | 120.5 | 21.1 |
| Induced Labor Income | -20.7 | 81.4 | 33.1 |
| Total Labor Income | -87.9 | 344.6 | 140.8 |
| <i>Impact Measure</i> | | <i>Distribution</i> | <i>Testing</i> |
| Employment | | <u>Number of Jobs</u> | |
| Direct Employment | -504 | 464 | 2,133 |
| Indirect Employment | -252 | 571 | 325 |
| Induced Employment | -378 | 485 | 609 |
| Total Employment | -1,135 | 1,513 | 3,068 |

Source: Values were estimated by UC AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.5c. Combined differences in economic contributions of the medicinal and adult-use cannabis segments, between the Taxation Baseline and proposed higher-security Bureau regulations

| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
|-------------------------------|----------------------------|------------------------|-------------------------|
| Value of Sector Output | | <u>Millions of USD</u> | |
| Direct Output | -179.6 | 265.3 | 406.3 |
| Indirect Output | -72.2 | 186.4 | 115.8 |
| Induced Output | -102.2 | 145.1 | 191.0 |
| Total Output | -354.1 | 596.8 | 713.4 |
| Value Added | | | |
| Direct Value Added | -122.3 | 91.5 | 316.1 |
| Indirect Value Added | -44.7 | 335.1 | 72.7 |
| Induced Value Added | -61.1 | 250.9 | 114.2 |
| Total Value Added | -228.0 | 851.3 | 503.0 |
| Labor Income | | | |
| Direct Labor Income | -85.3 | 88.1 | 173.1 |
| Indirect Labor Income | -29.5 | 224.0 | 42.3 |
| Induced Labor Income | -35.4 | 151.2 | 66.2 |
| Total Labor Income | -150.4 | 640.5 | 281.6 |
| <i>Impact Measure</i> | <i>Distribution</i> | <i>Testing</i> | <i>Retailing</i> |
| Employment | | <u>Number of Jobs</u> | |
| Direct Employment | -862 | 863 | 4,266 |
| Indirect Employment | -431 | 1,061 | 650 |
| Induced Employment | -647 | 902 | 1,219 |
| Total Employment | -1,940 | 2,812 | 6,135 |

Source: Values were estimated by UC AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

10. Lessons from other states: Colorado and Washington

Other states that have had medicinal cannabis available for many years and have legalized adult uses cannabis recently may provide information about the economic effect of cannabis policy changes in California. Colorado and Washington both had longstanding legal medicinal cannabis systems in place prior to legalization and regulation of adult-use cannabis. This allows for both states to provide a useful comparison to California.

First, we will discuss estimates of the size of the cannabis markets in Colorado and Washington, and what we can learn of use to California from those estimates. Then we will discuss the regulatory environment in these states and how they compare to California's. Throughout, we consider the ways in which California differs from Colorado and Washington, and lessons these differences may have for our estimates for California.

To consider the effects of regulations on the cannabis market in California, we must first consider the scope of the market. We do this by estimating consumption and production of cannabis in Colorado and Washington, and using these values to inform our assumptions about consumption in California. Utilizing results and methodology developed in two studies, and using data from the National Survey on Drug Use and Health (NSDUH), we have considered several possible scenarios for consumption of cannabis in California.

For guidance on our consumption assumptions about California, we relied on methodology introduced in the RAND study focusing on Washington and the Colorado Department of Revenue study.^{159,160} These studies begin with the adult population of the state in a given year, then use data on the percent of adults who report having used

¹⁵⁹ Kilmer, Beau, et. al. *Before the Grand Opening: Measuring Washington State's Marijuana Market in the Last Year Before Legalized Commercial Sales*. Santa Monica, CA: RAND Corporation. 2013.

https://www.rand.org/pubs/research_reports/RR466.html.

¹⁶⁰ Light, M.K., A. Opens, B. Lewandowski and T. Pickton. 2014. Market Size and Demand for Marijuana in Colorado; Prepared for the Colorado Department of Revenue. The Marijuana Policy Group. Denver, CO.

cannabis in the previous year from the NSDUH to find an estimated number of adult users for that year.

Using additional data from the NSDUH, we are also able to determine the number of monthly users of cannabis, which can further be broken down into the number of users who use cannabis less than once a month, one to five times a month, and so on. This provides us with a distribution of users by frequency of use.

Several studies that utilize NSDUH data conclude that an adjustment factor for underreporting is necessary to capture the true user prevalence (Marijuana Policy Group, 2014). The various studies cite underreporting due to unwillingness to admit to using a federally illegal substance, presence of user population outside the sampling framework of NSDUH, and purposeful or mistaken misrepresentation of cannabis use. We base our adjustment factors for underreporting on RAND estimates, and apply them to each group of users by frequency. The adjustment factors we use for each group are shown in Tables 10.1 (for Colorado) and 10.9 (for Washington). For groups of users up to 20 days per month, we assume 22% underreporting rates. We assume a lower underreporting rate of 11% for heavy users (more than 21 days per month) because it is recognized that underreporting is likely to be less prevalent among heavy users.

10.1 Colorado consumption and market size

In 2016, the U.S. Census Bureau estimated that the adult population of Colorado, over 18 years of age, was 4.2 million. The NSDUH reports that over the 2014-2015 survey period, 24 percent of adults 18 and over in Colorado report using marijuana in the last year and 17 percent in the last month.¹⁶¹ Estimated numbers of annual and monthly users, adjusted for under-reporting, are reported in Table 10.1.

¹⁶¹ Center for Behavioral Health Statistics and Quality. (2016). *2015 National Survey on Drug Use and Health: State-Specific Tables*. Substance Abuse and Mental Health Services Administration, Rockville, MD.
<https://www.samhsa.gov/data/sites/default/files/NSDUHsaeStateTabs2015B/NSDUHsaeSpecificStates2015.htm>

Table 10.1. Distribution of Colorado cannabis users by frequency of consumption per month

| Consumptions per month | Share of Total | Users per category | Adjustment for Underreporting | Adjusted users per category |
|-------------------------------|-----------------------|---------------------------|--------------------------------------|------------------------------------|
| < 1 | 28.4% | 278,000 | 22% | 356,000 |
| 1 to 5 | 23.9% | 235,000 | 22% | 301,000 |
| 6 to 10 | 7.3% | 72,000 | 22% | 92,000 |
| 11 to 15 | 3.1% | 30,000 | 22% | 38,000 |
| 16 to 20 | 5.6% | 56,000 | 22% | 72,000 |
| 21 to 25 | 8.6% | 84,000 | 11% | 94,000 |
| 26 to 31 | 23.1% | 228,000 | 11% | 256,000 |
| Totals | 100% | 984,000 | 19% | 1,209,000 |

Source: Total number of cannabis users in Colorado and cannabis users by frequency of use per month is calculated using data from the National Survey of Drug Use and Health.

The Colorado Department of Revenue study also conducted an additional survey of the amount of cannabis used by different frequency users. From these responses, we can estimate a total amount of cannabis used annually for each user type. Using the estimated numbers of each user type, we can then produce an aggregate value for estimated cannabis consumed. These results are shown in Table 10.2.

Table 10.2. Ounces of Cannabis Consumed per Day by Frequency of Use Category

| Consumptions per month | Median quantity consumed per day (oz dried flower) |
|-------------------------------|---|
| < 1 | 0.0106 |
| 1 to 5 | 0.0236 |
| 6 to 10 | 0.0236 |
| 11 to 15 | 0.0236 |
| 16 to 20 | 0.0236 |
| 21 to 25 | 0.0564 |

| | |
|----------|--------|
| 26 to 31 | 0.0564 |
|----------|--------|

Source: The Marijuana Policy Group (2014)

A study produced for the Colorado government used responses from the NSDUH to determine a breakdown of frequency of use among monthly users, as well as data collected from a survey taken in Colorado to estimate ounces per use by each user type, to estimate consumption in Colorado.¹⁶² Using this same method, aggregating the results from Tables 10.1 and 10.2, we estimate that adult cannabis users in Colorado over 18 consume about 456,000 pounds of cannabis per year, which is equivalent to about 6.2 ounces per user and about 1.74 ounces per capita adult population 18 and over in Colorado.

Based on Colorado tax data, we have estimated that there was about 444,000 pounds of cannabis produced in the legal system in the 2016-2017 fiscal year. Given that both values are estimates, this indicates that production in Colorado is roughly keeping up with use. It is likely that some share of legal sales are purchases from out-of-state visitors, but it is difficult to estimate this amount. The calculation of legal sales from tax data is discussed further in the following section. Colorado use rates for cannabis are higher relative to the U.S. as a whole.

If California cannabis use ends up similar to what Colorado was in 2015 after regulation, then consumption in California would be about 3.25 million pounds.

In terms of market size, the state of Colorado does not collect or report cannabis production or use data. It does report monthly tax data on the sale of cannabis and cannabis products. These data provides some information on the size of the cannabis market within the state. Using these data, and applying some plausible assumptions about cannabis consumers in Colorado, it is possible to estimate per-capita expenditure and volume of consumption for the adult population in Colorado over a twelve-month period.

¹⁶² Light, M.K., A. Opens, B. Lewandowski and T. Pickton. 2014. Market Size and Demand for Marijuana in Colorado; Prepared for the Colorado Department of Revenue. The Marijuana Policy Group. Denver, CO.

First, it is useful to distinguish between the separate taxes paid to the state of Colorado by cannabis consumers and industry. There are three state-level taxes assessed in Colorado: a 2.9% sales tax assessed to consumers on the sale value of all tangible items sold at medicinal cannabis retailers, a 10% additional sales tax to consumers of retail cannabis and cannabis-infused products, and a 15% excise tax assessed to industry on the value of retail cannabis as determined by the average market rate of cannabis. The average market rate is applied to sale of flowers, trim, wet whole plants, and seeds. The 10% additional sales tax to consumers is not applied when purchasing medicinal cannabis and cannabis-infused products.

Data on sales tax revenue collected from the initial 2.9% sales tax assessed to consumers on all tangible cannabis items sold by retailers is useful for estimating the share of total cannabis sales to consumers that occur in the medicinal and retail markets in Colorado. Table 10.3 provides analysis, by fiscal year, of sales tax revenue collected from medicinal and adult-use retailers in Colorado. The fiscal year in Colorado runs from July 1 to June 30 of each year. Legal sales of adult-use cannabis started on January 1, 2014, which was the first month that Colorado documented sales tax collected from cannabis retailers, including medicinal cannabis retailers. Although medicinal cannabis sales were legal in Colorado prior to January 2014, sales tax revenue from medicinal cannabis sales was not explicitly documented.

The first six months of 2014 show that the majority, approximately 62% of sales tax revenue generated in Colorado from cannabis sales was from medicinal cannabis retailers. Since the medicinal cannabis market was already established prior to January 2014, it is understandable that this segment would generate greater sales while the adult-use market was getting started. Over the next three fiscal years, the share of sales tax revenue collected from medicinal cannabis retailers declined compared to adult-use retailers. For the most recent fiscal year, July 2016 through June 2017, adult-use retailers generated 70% of total sales tax revenue compared to 30% for medicinal (Table 10.3).

Sales tax revenue generated from cannabis retailers in Colorado has grown annually since the start of the adult-use market in January 2014. Focusing on the last three full fiscal years, sales tax revenue grew from \$23 million in 2014-2015 to \$41 million in 2016-2017, an increase of 78 percent. Tax revenues for each period were generated from sales of \$796 million and \$1.42 billion, respectively.

Table 10.3. State Sales Tax Revenue, Total Revenue and Share of Total Revenue from Medicinal and Adult-Use Cannabis and Product Sales in Colorado by Fiscal Year

Numbers in millions of US dollars

| | <i>Medicinal</i> | <i>Adult-use</i> | <i>Total</i> |
|---|------------------|------------------|--------------------|
| Total tax revenue collected | | | |
| January 2014 to June 2014 | \$6 | \$3 | \$9 (six months) |
| July 2014 to June 2015 | \$11 | \$13 | \$23 |
| July 2015 to June 2016 | \$12 | \$20 | \$32 |
| July 2016 to June 2017 | \$12 | \$29 | \$41 |
| Total revenue earned | | | |
| January 2014 to June 2014 | \$194 | \$117 | \$311 (six months) |
| July 2014 to June 2015 | \$364 | \$432 | \$796 |
| July 2015 to June 2016 | \$422 | \$692 | \$1,114 |
| July 2016 to June 2017 | \$426 | \$992 | \$1,418 |
| Share of total cannabis revenue earned | | | |
| January 2014 to June 2014 | 62% | 38% | 100% |
| July 2014 to June 2015 | 46% | 54% | 100% |
| July 2015 to June 2016 | 38% | 62% | 100% |
| July 2016 to June 2017 | 30% | 70% | 100% |

Source: Colorado Department of Revenue

Note: Sales tax of 2.9% is charged on the sales value of all tangible items sold in adult-use and medicinal cannabis retailers, which include consumable cannabis products. Total revenue was calculated using reported sales tax revenue collected by the state of Colorado and dividing by the 2.9 percent sales tax rate applied to value of sales.

The Colorado cannabis industry is assessed a 15% excise tax on the assessed value of cannabis products. Estimated assessed value is based on a pre-determined Average Market Rate (AMR) for cannabis flowers, trim, wet whole plants and seeds.

The AMR is defined as the average price of all unprocessed retail cannabis that is sold or transferred from retail cannabis cultivation facilities in the state to retail cannabis product manufacturing facilities, retail cannabis stores or other retail cannabis cultivations. The AMR for each of these items is updated by the Colorado Department of Revenue every six months, and are listed in Table 10.4 for January 2014 through September 2017.

Table 10.4. Average Market Rate (AMR) of wholesale prices for assessment of 15% excise tax, January 2017 through September 2017 (US dollars)

| | <i>Flower (per pound)</i> | <i>Trim (per pound)</i> | <i>Immature Plant (per plant)</i> | <i>Wet Whole Plant (per pound)</i> | <i>Seed (per seed)</i> |
|----------------|-----------------------------------|-----------------------------|---|--|----------------------------|
| Jan-June 2014 | \$1,876 | \$296 | \$9 | N/A | N/A |
| July-Dec 2014 | \$1,876 | \$296 | \$9 | N/A | N/A |
| Jan-June 2015 | \$2,007 | \$364 | \$9 | N/A | N/A |
| July-Dec 2015 | \$1,868 | \$370 | \$8 | N/A | N/A |
| Jan-June 2016 | \$1,948 | \$464 | \$9 | N/A | N/A |
| July-Dec 2016 | \$1,816 | \$505 | \$10 | \$209 | \$2 |
| Jan-June 2017 | \$1,471 | \$499 | \$10 | \$223 | \$6 |
| July-Sept 2017 | \$1,298 | \$426 | \$4 | \$227 | \$3 |

Source: Colorado Department of Revenue.

Note: The Colorado Department of Revenue did not start collecting excise tax on sales of wet whole plant or seed until January 2016. Starting August 9, 2017 the excise tax will be assessed on the sale of contaminated product allocated for extraction at a rate of \$403 per pound. The Average Market Rate (AMR) beginning on July 1, 2017, will be in effect through September 30, 2017. The first AMR recalculation under the new statutory requirements will be effective on October 1, 2017, and at the beginning of each subsequent quarter on January 1, April 1, July 1, and October 1 each year.

Assessment of the 15% excise tax, along with the AMR set by the Colorado Department of Revenue provides the parameters to estimate the volume of cannabis in the Colorado legal markets. Estimating the volume of cannabis moving through the market using publicly available excise tax data requires making assumptions regarding the mix of products being moved. Data are not provided on the share of excise tax revenues collected for each of the assessed items.

We assume that the majority of excise tax, about 90%, is generated from the sale of flowers to retailers, followed by trim sales used in the manufacture of processed cannabis products sold at retail. The trade in wet plants and seeds is for home propagation or trade among commercial cultivators and can be considered cannabis products for future consumption.

Using these assumptions, we estimate the total pounds of usable cannabis that moved through the Colorado legal market from July 2016 through June 2017 using a share allocation of flower and trim sales ranging from 70% flower and 30% trim up to 90% flower and 10% trim. The parameters used and results of volume calculations are presented in Tables 10.5–10.7.

Table 10.5. Total Revenue from Cannabis Product Sales and 15% Excise Tax Collected, July 2016 to June 2017

| | <i>Excise Tax Collected (USD millions)</i> | <i>Revenue from Sales (USD millions)</i> |
|-----------------------|--|--|
| July to Dec 2016 | \$35.37 | \$235.79 |
| Jan to June 2017 | \$37.09 | \$247.28 |
| Total for Year | \$72.46 | \$483.07 |

Source: Colorado Department of Revenue.

Table 10.6. Average Market Rate for Flower and Trim to Assess 15% Excise Tax Collected, July 2016 to June 2017

| | <i>Flower AMR (USD per pound)</i> | <i>Trim AMR (USD per pound)</i> | <i>Weighted Average AMR</i> |
|------------------|---------------------------------------|-------------------------------------|---------------------------------|
| July to Dec 2016 | \$1,816 | \$505 | \$1,423-1,685 |
| Jan to June 2017 | \$1,471 | \$499 | \$1,179-1,374 |

Source: Colorado Department of Revenue.

Note: Weighted average AMR is author estimate assuming a range from 70%–90% flower and 10%–30% trim per usable pound of cannabis.

Table 10.7. Range of Estimates of Pounds of Usable Cannabis Sold in Colorado by Market Type, July 2016 to June 2017

| | Adult-Use Cannabis | Medicinal Cannabis | Total Cannabis |
|-----------------------|---------------------------|---------------------------|------------------------|
| July to Dec 2016 | 126,000-149,000 | 56,000-67,000 | 182,000-216,000 |
| Jan to June 2017 | 162,000-189,000 | 67,000-78,000 | 229,000-267,000 |
| Total for Year | 288,000-338,000 | 123,000-145,000 | 411,000-482,000 |

Source: Colorado Department of Revenue.

Note: The 15% excise tax is only collected on sales of cannabis products for the adult-use market in Colorado. Estimates of volume of cannabis products sold through the medicinal market are calculated using the share value of the 2.9% sales tax collected from medicinal retailers in Colorado.

People who purchase cannabis and cannabis products within Colorado, both residents and tourists to the state, consumed about 444,000 pounds of cannabis products during the fiscal year from July 2016 through June 2017. The volume data in Table 10.7, along with data on Colorado's adult population aged 18 and older from the Colorado State Demography Office, can be used to estimate per capita cannabis use in Colorado (Table 10.8).

Table 10.8 Per Capita Use of Usable Cannabis in Colorado, July 2016 to June 2017

| Parameter | Value |
|---|--------------|
| Volume of Cannabis Sold (in pounds) | 444,000 |
| Colorado adult population (18 and over) | 4,300,682 |
| Per capita use (in pounds) | 0.103 |
| Per capita use (in ounces) | 1.65 |

Source: Colorado Department of Revenue. Colorado adult population data comes from the Colorado State Demography Office.

10.2 Washington State consumption and market size

The adult population in Washington State in 2015 was estimated to be 5.5 million by the U.S. Census Bureau. According to the NSDUH, over the 2014-2015 survey period about 18 percent of respondents reported consuming cannabis in the past year, while about 11 percent reported using cannabis in the past month. Due to restrictions on data availability, we have used frequency of use estimates for Washington that are a weighted

average of Colorado use frequencies and U.S. use frequencies.¹⁶³ Replicating the procedure used to estimate consumption in Colorado, we have found an estimated annual consumption of about 389,000 pounds in Washington. Given the estimated adult users in Washington, this is about 0.33 pounds per user or 5.3 ounces per user. The distribution of Washington users is summarized in Table 10.9.

Table 10.9. Distribution of Washington Cannabis Users by Frequency of Consumption

| Consumptions per month | Share of Total | Users per category | Adjustment for Underreporting | Adjusted users per category |
|-------------------------------|-----------------------|---------------------------|--------------------------------------|------------------------------------|
| < 1 | 29.2% | 286,000 | 22% | 367,000 |
| 1 to 5 | 25.2% | 247,000 | 22% | 317,000 |
| 6 to 10 | 8.2% | 80,000 | 22% | 103,000 |
| 11 to 15 | 5.4% | 53,000 | 22% | 68,000 |
| 16 to 20 | 5.4% | 53,000 | 22% | 68,000 |
| 21 to 25 | 7.2% | 71,000 | 11% | 80,000 |
| 26 to 31 | 19.4% | 190,000 | 11% | 213,000 |
| Totals | 100% | 981,000 | 19% | 1,216,000 |

Source: Total number of cannabis users in Washington and cannabis users by frequency of use per month is calculated using data from the National Survey of Drug Use and Health.

Note: The weighted average share of total column is calculated as described in footnote 6.

The Washington State Liquor and Cannabis Board (LCB) reports data on usable cannabis production (flowers) and cannabis extract production. Converting the extract production weight back to an equivalent flower weight gives an approximate total production of legal adult use cannabis of about 134,000 pounds in Washington.¹⁶⁴ Given that medicinal

¹⁶³ From available NSDUH data, we have determined that Washington use rates are between U.S. and Colorado rates. For example, Washington annual use of 18% is between the 13% national rate and the 24% Colorado rate. Note that if the Washington frequency of use distribution is closer to that of Colorado, actual consumption will be higher than we have estimated, and actual consumption will be lower if frequency of use more closely resembles the U.S.

¹⁶⁴ Conversion of concentrate weight to usable cannabis weight assumes that 1 pound of concentrate is equivalent to about 5 pounds of usable cannabis. This assumes 15% potency usable cannabis being used to produce 75% potency concentrate. Estimated conversion rates vary widely across industry sources, ranging from a 1:5 ratio to a 1:10 ratio or higher. Colorado equivalency guidelines assume concentrates are about 10-20% of usable weight, depending on the solvent used (Colorado Department of Revenue, "Marijuana Equivalency in Portion and Dosage," August 10, 2015). Available at: https://www.colorado.gov/pacific/sites/default/files/MED%20Equivalency_Final%2008102015.pdf. Interviews with concentrate processors has also indicated a 1:10 ratio of concentrate to usable weight (Crombie, Noelle. "Oregon's hot hash oil market drives demand for marijuana 'trim'". *The Oregonian* August 24, 2015. Available at:

cannabis production in Washington remained unregulated in 2015, this production value does not include any production of legal medicinal cannabis. Therefore, it is difficult to estimate the size of the illegal market relative to the medicinal market. Of the 255,000 pounds unaccounted for in the production data reported by the LCB, we have estimated that 144,000 pounds were consumed in the medicinal market and about 111,000 pounds in the illegal market.

In 2016, the medicinal and adult-use markets were merged in Washington. Using 2016 population data we have estimated total consumption of 397,000 pounds.¹⁶⁵ If we examine total legal production reported by the LCB for from June 2016 through May 2017, including cannabis used in both adult-use and medicinal products, is about 381,000 pounds.¹⁶⁶ This leaves about 16,000 pounds of consumption unaccounted for. Although estimates for the illegal market in 2015 are uncertain, this estimate indicates that a significant portion of medicinal consumers shifted to the legal adult-use market, and the share of the illegal market continued to decline as adult-use production expanded to meet consumption.

If California consumption were proportional to the 2016 estimates from Washington, it would be about 2,048,000 pounds.

A study published in 2013 by the RAND Corporation, after the passage of Initiative 502 but prior to the legalization of adult-use cannabis sales, estimated median 2013 consumption

http://www.oregonlive.com/marijuana/index.ssf/2015/08/marijuana_trim_goes_from_garba.html). One cooking calculator considered used the percent THC of the usable cannabis to determine the conversion rate, as we have done here (MassRoots, "Cannabis Cooking Calculator." November 21, 2014. Available at: <https://www.massroots.com/news/cannabis-cooking-calculator?is=1>). The actual quantity of cannabis produced depends on the true conversion rate. If the conversion rate is closer to 1:10, then actual production is higher than the estimated values reported here.

¹⁶⁵ Note: This estimate does not include updated use rates from the NSDUH, given that 2016 survey results have not been released as of yet. If use rates have continued to increase as a result of legalization than estimated consumption would be higher. However, use rates in Washington actually declined from 2014 to 2015, and 2015 rates were consistent with 2013 use rates, so it is possible that use rates will remain unchanged in 2016.

¹⁶⁶ Note: Though the merger of the medicinal and adult use markets occurred after July 1, 2016, the period from June 2016 to May 2017 is the most recent 12-month period available, and primarily covers the period in which the markets were merged.

of cannabis in Washington of 175 metric tons, or 386,000 pounds.¹⁶⁷ This study rejects a previous estimate by the Washington Liquor and Cannabis Board (LCB) of 85 metric tons of consumption, or 187,000 pounds. The LCB estimate relied upon survey data from the 2008-2009 National Survey on Drug Use and Health (NSDUH).

Using our own estimation methods, which are an extension of methods in the RAND study, we have estimated Washington cannabis consumption for 2010 and 2013. Our estimate for 2010 provides a case in which only the medicinal market and the illegal market were present, while 2013 provides a comparison in which adult-use was legal, but not yet commercialized.

We estimate that consumption for 2010 was about 259,000 pounds, while 2013 consumption was about 354,000 pounds. If we assume that at this point the total market consisted of about 60 percent medicinal and 40 percent illegal, that would result in a medicinal market of about 155,000 and a black market of about 104,000 pounds in 2010.¹⁶⁸ Doing the same for 2013, we find a medicinal market of about 213,000 pounds and an illegal market of about 142,000 pounds.

A study by the BOTEC Analysis Corporation from 2015 estimated a total cannabis market size at \$1.33 billion.¹⁶⁹ This includes \$480 million from the medicinal cannabis market (37 percent), \$460 million from the adult-use market (35 percent), and an illegal market of \$390 million (29 percent).¹⁷⁰ However, given the range of uncertainty around their

¹⁶⁷ Kilmer, Beau, et. al. *Before the Grand Opening: Measuring Washington State's Marijuana Market in the Last Year Before Legalized Commercial Sales*. Santa Monica, CA: RAND Corporation. 2013. https://www.rand.org/pubs/research_reports/RR466.html.

¹⁶⁸ Note: The split of 60% medicinal and 40% illegal was chosen because of the shares estimated for 2015. Using these splits, it assumes that most of the shift to adult use came from the medicinal market, while the illegal market decreased, but not to the same extent that the medicinal market did.

¹⁶⁹ Kleiman, Mark A.R., et. al. *Estimating the Size of the Medical Cannabis Market in Washington State*. Los Angeles, CA: BOTEC Analysis. December 15, 2015. <http://lcb.wa.gov/publications/Marijuana/BOTEC%20reports/BOTEC-MMJ-Report.pdf>.

¹⁷⁰ Note: In July 2016, the medicinal and adult use cannabis markets in Washington were merged. This change has resulted in a diminished medicinal cannabis market. However, in order to compare these results to California, we will be considering market shares prior to this change.

estimates, they estimate that the black market could be up to 48 percent of the total cannabis market.

Continuing with the estimation method that we used previously to produce estimates of the cannabis market for 2010 and 2013, we have also estimated total consumption in 2015. Compared to the previous two estimates, 2015 provides a case in which adult-use has been commercialized, and an adult-use cannabis market now exists alongside the medicinal and illegal markets. We estimate a market of about 389,000 pounds in 2015. Using data from the LCB, we have estimated legal production of adult-use cannabis in 2015 at about 134,000 pounds, which is about 35 percent of the overall market. This is consistent with the estimates from the BOTEC study of the size of the adult-use market. Using the other shares that they have estimated, along with our estimates of total consumption, we find a medicinal market of about 144,000 pounds and an illegal market of about 111,000 pounds.¹⁷¹

These potential market share scenarios reflect the inherent uncertainty surrounding estimation of the medicinal market and especially the illegal market in Washington State. Prior to July 2016 no data on medicinal cannabis production was collected, meaning that it is difficult to estimate what share of consumption was met by the medicinal market. We expect that the medicinal market remained larger than the adult-use market, given that the medicinal market remained unregulated and was not subject to taxes beyond the state sales tax, and our estimates under both scenarios outlined above are consistent with this expectation. Our estimates of the illegal market assume that any remaining consumption that is not met by the adult-use or medicinal markets is met by the illegal market. This means that these estimates are inherently reliant on the accuracy of the estimation of the medicinal market.

¹⁷¹ Note: Washington state sales tax data indicates that, based on total value of sales, the adult use market is 75% of legal sales and the medicinal market is 25% of legal sales. Using this information along with our estimates of consumption, it would imply that 35% of the cannabis market is adult use, 9% medicinal, and 57% illegal. However, these estimates are considered unlikely, given that the medicinal share of taxable sales is likely underreported. Washington State Department of Revenue, "Recreational Marijuana Taxes," http://dor.wa.gov/Content/AboutUs/StatisticsAndReports/stats_MJSalesTaxes.aspx.

The total consumption estimates for 2010, 2013, and 2015 are collected in the table below, alongside the estimated shares for each market component. If we compare these three estimates, we can see that cannabis consumption has risen consistently over time, with the growth in the medicinal and illegal markets from 2010 to 2013 reflecting this. Upon commercialization of adult-use, however, we see that a significant amount of consumption shifts from the medicinal market and the illegal market to the adult-use market. This is consistent with expectations and evidence from other studies and reports. Despite this shift, both the medicinal and illegal markets remain sizeable in 2015.

If consumer reactions to the opening of the adult-use market are similar in California to those in Washington, some consumers will switch from both the medicinal and illegal markets to join the adult-use market. This will increase the share of the adult-use market, but it will not necessarily overtake the other two. In Washington, it is estimated that the medicinal market remained the largest component of the overall cannabis market until reforms merged the medicinal and adult-use markets in 2016. The breakdown between each in 2010, 2013, and 2015 is shown in Table 10.10. Depending on the structure of regulations implemented on the adult-use cannabis market, it could remain small relative to the medicinal and illegal markets.

Table 10.10. Washington State Cannabis Consumption Estimates for 2010, 2013, and 2015

| | Total Consumption | Medicinal | Adult-use | Illegal |
|------|------------------------------|---------------------------|------------------|----------------------------|
| 2010 | 259,000 (203,000–318,000) | 129,000-181,000 50-70% | -- -- | 78,000-129,000 30%-50% |
| 2013 | 354,000 (278,000–435,000) | 177,000-248,000 50-70% | -- -- | 106,000-177,000 30%-50% |
| 2015 | 389,000 (305,000–478,000) | 144,000 37% | 134,000 35% | 111,000 28% |

Note: For 2010 and 2013, the share of total consumption attributed to medicinal and illegal markets are estimates. Medicinal, adult-use, and illegal estimates are calculated from the median consumption estimate.

10.3 Illegal cannabis in Washington

According to data from the National Seizure System (NSS), a collection of reports of drug seizures from law enforcement agencies across the country, cannabis originating in Washington State has been seized in 43 other states since legalization in 2012 through 2015.¹⁷² In contrast, in 2010 and 2011 seizures of Washington cannabis occurred in 35 states, indicating a potential increase in distribution since legalization. While the number of seizures occurring annually remained consistent between 2010 and 2015, an average of about 60 incidents per year, there was a significant spike in the total pounds seized in 2012, at around 34 pounds per seizure. The amounts seized returned to a lower level from 2013 on, with around 10 pounds seized per incident. In total 3,619 pounds of cannabis from Washington was seized in other states between 2012 and 2015.

Some reports from in-state, however, indicate that illegal production is decreasing. The Drug Enforcement Agency (DEA) reports that in 2014, 635 pounds of cannabis was seized, a decrease of about 80 percent from the 3,126 pounds seized in 2010.¹⁷³ A total of 423 grow operations were recorded by the DEA in 2010, falling to 153 with legalization in 2012, and continuing to fall to 88 operations in 2014. This would seem to indicate that many operations began to shift from illegal to legal production after legalization in 2012, and shifts continued upon commercialization in 2014. The decrease in seized cannabis would also be consistent with this result. Based on the information from the NSS and the DEA, it seems that while production has shifted from illegal to legal in Washington, existing illegal production has continued with more product being shipped out of state.

Popular press articles in Seattle have indicated that illegal sales, both wholesale and individual, are continuing for many reasons.¹⁷⁴ Large price differences exist between wholesale cannabis sold within Washington and cannabis sold in states where cannabis is

¹⁷² Source: <http://www.riag.ri.gov/documents/NWHIDTMarijuanaImpactReportVolume1.pdf>.

¹⁷³ Faulk, Mike. "Illegal marijuana production has plummeted in Washington since 2010" *Yakima Herald* March 23, 2016. http://www.yakimaherald.com/news/local/illegal-marijuana-production-has-plummeted-in-washington-since/article_a90b32f8-f0c5-11e5-b15e-1b5cf3ea6c5a.html

¹⁷⁴ Coughlin-Bogue, Tobias. "Four Years After Legal Weed, Seattle's Black Market Still Thrives" *Seattle Weekly* September 21, 2016. <http://www.seattleweekly.com/news/four-years-after-legal-weed-seattles-black-market-still-thrives/>

still illegal. For example, a pound of cannabis could be sold for around \$1,400 in Washington or \$3,500 in another state. This is consistent with the evidence from the NSS indicating that more cannabis is being moved out of Washington. Retail cannabis prices are also higher than street level prices, with \$30 for an eighth ounce at retail compared to \$20 per eighth reported on the street. This could still cause consumers to purchase from the black market over retail stores, along with other conveniences that come with black market purchases such as delivery, ease of access, and longstanding relationships with dealers.

Given that illegal production in California is already high, we expect that production in California will remain large relative to other states. If current illegal operations in California behave similarly to those in Washington, we would expect some of those producers to become licensed, legal cannabis producers under the new regulations. This would result in a decrease in illegal cannabis production, even though overall production of cannabis would remain the same. In addition, if wholesale prices in California are low relative to states in which cannabis is still illegal, we may see an increase in illegal shipments out of California.

10.4 Regulations in other states

10.4.1 Cannabis Regulations in Washington. Upon the passage of Initiative 502, the voter-approved legislation authorizing adult-use cannabis, requirements were placed upon the to-be-established adult-use industry in Washington, while the medicinal cannabis market remained unregulated. Though some of these requirements have remained largely unchanged, significant regulatory changes were made in 2016 when the medicinal and adult-use markets were merged. This can primarily be seen in the product definitions, where the products that constitute medicinal cannabis have been limited.

Cannabis and products that must be tracked include seedlings, clones, plants, lots of usable marijuana or trim, leaves, other plant matter, batches of extracts, infused products, samples, and marijuana waste. These products must be traced from production,

through processing, and into retail. It must also be possible to identify which plot of usable cannabis was used to create a given batch of extract or infused products. Any plant that is greater than eight inches in height must be tagged and tracked individually, and all harvested cannabis and processed cannabis products must be tagged and tracked.

Specific information that must be reported includes key events, such as movement of a plant from one stage of growth to another, when plants are harvested or destroyed, when lots of cannabis or processed products are destroyed, when cannabis products are transported, and theft of any plants or products. A complete inventory of all plants, products, and wastes must be maintained at all times, along with sale records and excise tax records. There are also waiting periods specified before destruction of plants or products and transport of products.

All samples of cannabis must be tracked as well. This includes testing samples sent to a lab, free samples given to another licensed operation, samples for quality testing by the producer or processor, usable cannabis samples provided to retailers, and samples provided to the LCB for compliance checks. Licensees must also report results of quality assurance tests from lab testing.¹⁷⁵

Washington State regulations outline three product classifications: General use, high THC, and high CBD. These classifications cover all products that can be legally sold in Washington. While there is no further separation between adult-use and medicinal products, any high THC products may only be sold in retail stores with a medicinal endorsement.

The general use category covers all products with levels of THC and CBD below certain thresholds. Individual product servings may only be up to 10 milligrams of THC, while a unit may not contain more than 10 servings. These products may be purchased at any

¹⁷⁵ Traceability regulations are outlined in Washington Administrative Code 314-55-083.

<http://app.leg.wa.gov/WAC/default.aspx?cite=314-55-083>

retail location by any consumer over the age of 21, or any medicinal cannabis patient with a recognition card between 18 and 20.

A product labeled as high THC may contain more than 10 milligrams of THC per serving, but no more than 50 milligrams. This product category is much more limited in terms of potential products, however. High THC products may only be capsules or tablets, tinctures, transdermal patches, or suppositories. This means that high THC infused edibles are not compliant under Washington regulations. These products may only be sold in retail stores with a medicinal endorsement, and may only be purchased by patients over 18 years old with recognitions cards or by designated providers.

Cannabis products labeled as high CBD are any products that have a higher ratio of CBD to THC. This product category excludes usable marijuana, thus cannabis intending for smoking cannot be labeled as high CBD. Cannabis extracts may contain no more than 2 percent THC by weight, and must have at least 25 times higher CBD concentration, while edible products and topical products must contain as least 5 times higher CBD concentration than THC. High CBD products may be sold in any retail market and may be purchased by the same consumers as general use products.¹⁷⁶

10.4.2 Cannabis regulations in Colorado. Colorado also mandates a track and trace system on all legal cannabis from seed to final purchase. The Inventory Tracking System requires seed-to-sale tracking of retail cannabis from either the seed or immature plant stage until the retail cannabis or retail cannabis product is sold to a customer at a retail cannabis store or is destroyed. At least one associated key licensee of a retail cannabis establishment or an occupationally licensed employee of a retail cannabis establishment must be designated the Inventory Tracking System Trained Administrator. This individual must attend and successfully complete Inventory Tracking System training and any

¹⁷⁶ Cannabis product definitions are outlined in Washington Administrative Code 246-70-040. <http://app.leg.wa.gov/WAC/default.aspx?cite=246-70-040>

additional training required by the Colorado Department of Revenue, Marijuana Enforcement Division.

In addition, each employee, who is granted a user account to the Inventory Tracking System must be successfully trained by an Inventory Tracking System Trained Administrator in the proper and lawful use of Inventory Tracking System. A Licensee that operates both a medicinal cannabis business and retail cannabis establishment within one location is required to maintain separate and distinct inventory tracking processes for medicinal cannabis and retail cannabis inventories. The inventories must be clearly tagged or labeled so that the product can be reconciled to a particular medicinal cannabis business or retail cannabis business.

All employees of a licensed cannabis operation are required to display identification at all times, including while transporting cannabis or cannabis products and while on the operation premises. Visitors to a licensed operation must also wear identification while on the premises, with details including the purpose of their visit documented (this does not include customers at retail stores).

Licensed premises must also maintain alarm and surveillance systems. Areas that must be covered by the surveillance system include anywhere that cannabis is grown, cannabis product or waste is moved, processed, stored, or destroyed, any point of sale areas, and exterior perimeters and entry points. Cannabis and cannabis products that will be moved or transported between facilities must be quarantined for at least 24 hours.¹⁷⁷

A Colorado Medical Marijuana Card (MMC) is required to purchase cannabis products in the medicinal market. To be eligible for an MMC one must be a Colorado resident, be 18 years or older and have a qualifying medical condition. Qualifying medical conditions include cancer, glaucoma, HIV or AIDS, cachexia, persistent muscle spasms, seizures, severe nausea, severe pain or post-traumatic stress disorder. To apply an individual must

¹⁷⁷ Other security regulations are outlined in Washington Administrative Code 314-55-083.

<http://app.leg.wa.gov/WAC/default.aspx?cite=314-55-083>

see their physician and have the physician certify that the individual is eligible for an MMC. Once physician certification is obtained the individual can apply online or by mail for an MMC. The cost of applying for or renewing an MMC is \$35.00 per year.

10.5 Concluding lessons for California

California had an estimated over-18 population of about 30 million in 2016 according to the U.S. Census Bureau. The NSDUH estimates that about 15 percent of the over-18 population in California use cannabis annually, and about 10 percent use monthly.

As we did with Washington, we can use a weighted average of Colorado frequency use data and U.S. frequency use data to produce a comparison that may be useful for California.¹⁷⁸ Based on these use rates, annual consumption would be 1.7 million pounds in California, which is about 0.32 pounds per adult user. This would suggest that pounds per user in California is close to that in Washington.

If we assume that the share of the total market that is covered by medicinal and adult-use is similar to Washington shortly after legalization and commercialization, then about 70% of consumption would be covered by legal production, while about 30% of consumption would be unaccounted for. If these coverage shares are accurate, then this would imply an illegal market of about 512,000 pounds. This means that the illegal market in California alone would still be larger than total consumption in Colorado or Washington. These numbers provide some additional context for the AIC estimates of California consumption used in other chapters.

11. Brief historical review of alcohol control in the United States, with potential lessons for the impact of cannabis regulations

¹⁷⁸ California use rates are about 15-20% between Colorado and U.S. use rates. For example, annual use rates in California are 15%, which is about 20% between the 13% U.S. use rate and 24% Colorado use rate.

The United States has a long history of legislation designed to control alcohol consumption. From 1919 through 1934, the commercial production and distribution of beverage alcohol was illegal, and alcohol control is the subject of both the 18th and 21st Constitutional amendments (Pinney, 2005). Issues surrounding how to incorporate alcohol into society are not dissimilar to those facing state and local governments as they move to license, regulate and label medicinal cannabis in California (Mendelson, 2009).

Beverage alcohol and medicinal cannabis are, of course, very different products, but issues of licensing, taxation, separation of producer from retailer, local control of production and sales and labeling are similar for beverage alcohol and medicinal cannabis. Alcohol is a heavily regulated product and such regulation adds costs that in turn effect both demand and supply. A review of alcohol regulation in the United States, and particularly in California, may have lessons for the regulation of medicinal cannabis.

11.1 Prohibition

National prohibition of alcohol was quite different from the criminalization of cannabis. The Eighteenth Amendment prohibited the production, distribution, and sale of most alcoholic beverages. However, it did not criminalize the possession or consumption of alcohol. Individuals with private cellars stocked with pre-Prohibition alcohol could legally consume those beverages at home and serve them to guests, although they could not legally transport the beverages to another location.

Nor were all forms of alcohol illegal to produce. The Volstead Act, which was the Congressional legislation designed to enforce the 18th Amendment, allowed for the production of “non-intoxicating” fruit juices produced from apples and grapes. Up to 200 gallons of wine per family could legally be produced each year and consumed on-site and shared with guests. Unlike wine and hard cider, the production of beer and distilled spirits

was illegal, and it was these two forms of beverage alcohol that were produced or smuggled into the country and sold.

Some of the legally-produced wine for home consumption was likely diverted into the illegal distribution system, just as some medicinal cannabis is probably resold to individuals without medicinal cannabis cards, but the volume is unknown and wine was not the focus of government enforcement, which centered on distilled spirits (Mendelson, 2009; Pinney, 2005).

The legality of home wine production had a curious effect that may have parallels with medicinal cannabis, in that it spurred grape production. Because wine was the major legal form of alcohol during Prohibition, demand for wine, and for wine grapes, increased. Grapes that had sold for \$30 per ton in 1919 were sold for \$100 per ton the following year. The high prices sparked a winegrape planting boom, and winegrape acreage in California almost doubled from 98,500 acres in 1920 to 188,000 acres in 1930. The high prices only lasted for a few years, until quantity produced from the new plantings met quantity demanded, at which point winegrape prices fell to pre-Prohibition levels.

However, as is often the case in agricultural booms, the actual acreage of new vineyards exceeded the acreage needed to meet demand, and prices fell to \$18 per ton by the late 1920s (USDA, 2014). Even after the repeal of Prohibition, low grape prices caused low profitability among growers, although not so low as to cause vineyard removals.

By 1938, low prices led the winegrape industry to mandate the distillation of 45% of the 1938 crop in an effort to stabilize winegrape prices (Pinney, 2005). Of course, winegrapes are perennial crops and, once planted, will produce for many years, whereas cannabis is an annual crop and growers can more quickly adjust supply relative to demand. However, investments in indoor growing facilities or land represent real costs that will only be recouped if used. Such investment may cause growers to continue to produce crop even at low prices. As growers respond to an increased demand that may follow the regularization of medicinal cannabis, limitations on the size of cannabis farms may result

in an increased number of individual firms entering the industry, rather than the expansion of existing firms.

11.2 Repeal and taxation

Although by 1930 many Americans had concluded that Prohibition was a failure, more than a quarter of the states wished to continue some form of alcohol business ban and could thus block the Constitutional amendment that was necessary in order to repeal the 18th Amendment. The political compromise that was reached in the form of the 21st amendment was that each state was given the right to control production and distribution of alcoholic beverages.

As a consequence, the United States effectively became 50 countries, each controlling alcohol in different ways and taxing at different rates. Some states, such as Oklahoma and Mississippi, maintained Prohibition for many years. Others, such as Utah and Pennsylvania, became what is termed “control states” and created a system in which the state was the importer, wholesaler and retailer of alcoholic beverages. Most states created a system in which private firms were licensed by the state to perform specific functions, such as production, wholesaling or retailing, generally separating retailing from other activities. This system, often referred to as the “three-tier” system, is addressed in greater detail later in this report (Mendelson, 2009).

One key point of State control was and is taxation. Each state taxes various alcoholic beverages at differing rates, often based on the concentration of the alcoholic beverage. In California, for example, distilled spirits under 100 proof (50% concentration) pay an excise tax of \$3.30 per gallon; beer, wine and hard cider, on the other hand, pay \$0.20 per gallon. The economic Law of Demand stipulates that all other things being equal, price increases will decrease the quantity consumed of a good. If price decreases, on the other hand, consumption will go up. In 1890, the Federal government eliminated the \$0.90 a gallon excise tax on brandy used in fortifying wine for the production of dessert wines. Prior to 1890, fortified wine constituted about 5% of California’s total wine production.

Without excise taxes, fortified wine prices fell and fortified wine quickly became the least expensive form of beverage alcohol available to consumers. By the early 20th century, fortified wine accounted for over 40% of California's total wine production (West, 1935).

Taxes do change consumer behavior. There are numerous examples of consumers crossing state borders to purchase goods in a low-tax state. A 2011 study of consumer behavior in West Virginia concluded that consumers close to Kentucky and Ohio, whose tax rates on alcohol were lower than those of West Virginia, sometimes traveled out of state to purchase alcohol, resulting in lower sales and tax revenue for West Virginia counties adjoining Kentucky or Ohio (Nesbitt and King-Adzima, 2011). Conversely, the West Virginia counties bordering Virginia, whose alcohol tax rates are higher than those of West Virginia, benefited from Virginia consumers crossing the border into West Virginia to purchase alcohol.

Anecdotal examples of consumers crossing borders to purchase alcohol and illegally smuggling their purchases back into their home state abound. In 2009 a Massachusetts legislator who had voted for a tax increase on alcohol was arrested smuggling alcohol purchased in New Hampshire, where alcohol taxes were lower (Henchman, 2009). Pennsylvania, which has a state monopoly on alcohol sales, and thus higher prices for similar products than in New Jersey or Delaware, has actively enforced searches of cars entering the state in an attempt to reduce liquor smuggling (Patch Staff, 2013).

Given observed behavior of consumers of alcohol, some cannabis consumers may travel from a high-cost area to a low-cost area for cannabis. Since this would occur intra-state, it would be legal from a state perspective, but it would reduce the volume of sales in the high-cost area. These effects may be considered by municipalities and counties when setting local requirements for cannabis licensing, but it is of course impossible for us or for the Bureau to predict the future actions of local municipalities with respect to the taxation of cannabis.

11.3 Three-tier distribution

Prior to Prohibition, a major concern of temperance advocates was the so-called “tied house” where a producer or supplier also owned the retail establishment, generally a saloon. The concerns were that vertical integration reduced alcohol prices, thus encouraging consumption, and that vertical integration tended to create large-scale enterprises that dominated independent retailers. Mendelson (2009) reports that by 1900, perhaps 80 percent of saloons in the United States were owned by brewers or distillers. Following the repeal of Prohibition, the Federal government and most states adopted what were called “tied-house” laws, which prohibited a supplier or wholesaler from also being a retailer. Although the original issue had been with on-sale establishments such as saloons or bars, most tied-house laws enacted after Prohibition included off-sale retail stores as well.

States differ in how rigorously they apply separation of licenses. Some states separate each tier and restrict the number of licenses that can be owned by a single entity. Colorado, for example, only allows one license per individual or company. Colorado requires an importer’s license for companies bringing alcohol into the state. The importer pays state excise taxes and can only sell to a wholesaler. The wholesaler buys product from in-state producers or from importers and can only sell to retailers. Colorado retailers may only buy from wholesalers, can sell only to consumers and can only hold a retail license for one location—thus Whole Foods can sell wine and beer at only one of its supermarkets in the state. Colorado’s restrictions on license ownership are unusually severe, but most other states attempt to separate production from distribution and retail (Lapsley, Alston and Sambucci, 2016).

Other states use pricing mechanisms in addition to the three-tier system to control prices and availability of alcoholic beverages. Some use “price posting” in which the producer or importer posts with the state agency minimum prices at which the product can be sold at wholesale, thus eliminating volume discounts to retailers.

Ohio, for example, requires that suppliers publicly “post” their price to wholesalers in a document filed with the Ohio Division of Liquor Control. Under Ohio law, wholesalers and retailers must use minimum markups, thus assuring that no discounts for volume purchases by retailers are allowed and that retailers will sell the same good for the same price across the state. The general rationale for such systems is that no single retailer or wholesaler can dominate or control the marketplace (Mendelson, 2009). The practical result is that Ohio consumers pay higher prices than in neighboring states (Conlon and Rao, 2015).

Until 1980, California had a similar system of price posting for wine, which was overturned by the California Court of Appeals in the Midcal-Aluminum decision (Mendelson, 2009). Alcoholic beverage retailing changed dramatically in California following the 1980 decision as firms such as Liquor Barn appeared on the California retail scene, offering lower prices and wider selections.

California generally uses the three-tier system, but, as the dominant U.S. producer of wine, has allowed wineries special privileges under the California Winegrower license since Repeal. The Winegrower license combines the rights found in several different licenses. A holder of a Winegrower license can crush and ferment grapes, produce wine, buy and sell bulk wine, import and export bulk and bottled wine, sell wine to wholesalers and retailers in state, sell its produced wine directly to consumers either at the licensed facility or via direct shipping, pour wine for consumers, and charge for the pour—but cannot own a retail establishment that sells alcoholic beverages produced by other manufacturers. Thus the holder of a California Winegrower license can act as a producer, importer, wholesaler, retailer, and bar, but is limited to only being able to sell its own products.

One of the stated goals of the three-tier system and tied-house laws was to prevent a single firm from dominating alcohol sales. In 2014, there were 4,286 licensed wineries in California. But most production and California sales was made by the three largest wine

firms: Gallo, Constellation, and the Wine Group, which collectively account for approximately 50% of U.S. sales. The top ten U.S. producers account for approximately 80% of all production and imports. Similar consolidation has occurred at the wholesale level, where the top 5 national wholesalers accounted for more than 50% of all sales by value in 2014.

The average small winery is quite small, producing perhaps 5,000 gallons of wine (Lapsley, Alston and Sambucci, 2016). Small wineries generally have difficulty in acquiring three-tier distribution, and many survive partly on the strength of direct sales to consumers who visit their winery or join their wine clubs. For these firms, the provision in the California Winegrower's license that allows direct sales to consumers is key to business success. In retrospect, there seems to be little data to indicate that tied-house laws and three-tier distribution have limited producer or retail consolidation. One consistent pattern is that in states in which retailers cannot purchase directly from producers or where price posting is maintained, consumers do pay higher prices (Conlon and Rao, 2015).

11.4 Local option and licensing

Although some states allow so-called “local option” at the county or city level for the retailing of alcoholic beverages, local option for alcohol retailing has not been allowed in California since Repeal. However, California has, in a sense, allowed de facto local option for medicinal cannabis, as the proposed regulations do not allow applicants to obtain state licenses until they have first been granted the permission to operate by their local counties or municipalities. Local option allows individual communities to decide whether or not they wish to allow cannabis cultivation and retailing in their county or city, but it also creates additional regulations and costs for firms, which should result in higher prices than if statewide regulations only are applied.

For a medicinal cannabis user located in a “dry” city or county, local option may also add cost in time and travel expense for the individual to visit a retailer in a community where sales are allowed. 34 states currently allow local option at the county level for alcohol

control, and it is estimated that approximately ten percent of counties, mostly in the Midwest and the South, ban the sale of alcohol. However, the general trend seems to be toward allowing alcohol sales. A 2014 study of 152 dry counties in the South and Midwest showed 40 changes in local option elections during the period from 1994- 2001, all moving toward allowing sale of alcoholic beverages (Billings, 2014).

Given the local option for medicinal cannabis sales, the lack of clear state-wide guidelines for issuing cultivation and retail permits may create complexities for firms. The California Department of Alcoholic Beverage Control was created by a State Amendment in 1954, taking control of licensing from the State Board of Equalization, members of which had engaged in “selling” of licenses (California, 2005). The California Alcoholic Beverage Control Board’s system of retail licensing linked to population density and type of license offers an objective and fair way to license retailers, while still considering local opinions.

11.5 Testing and labeling

Testing for alcohol concentration in wine is straightforward, relatively inexpensive, and easily performed in a winery laboratory. Federal law requires that wineries have some means to determine alcohol concentration, and the typical instrument is an ebulliometer, a device that calculates alcohol concentration of a liquid by measuring the liquid’s boiling point relative to the boiling point of water. Ebulliometers cost about \$1,000 and the test takes perhaps 10 minutes.

Two of the main reasons that the Federal government requires producers to test alcohol concentration in wine are that (1) wine is taxed differently depending upon alcohol concentration; and (2) wine labels must state alcohol concentration within the range of plus or minus 1.5% of observed alcohol. The testing does not need to be performed by an accredited third-party laboratory, and the process does not add appreciably to producer cost. The only check on label accuracy is performed by the Federal Tax and Trade Bureau (TTB) of the Department of Treasury, which conducts random product integrity audits that include testing of alcohol concentration.

Generally speaking, the incidence of label fraud with regard to state alcohol seems quite low for wine. Alston (2015) compared more than 91,000 alcohol label claims with alcohol levels analyzed by the Liquor Control Board of Ontario and found that the average actual alcohol concentration was 13.30% while the average alcohol content reported on the label was 13.16%.

Wine labels have evolved significantly from 1934, when a wine label might simply bear the name of the bottler, a semi-generic description of type such as “California Burgundy” or “New York Champagne,” and a statement of alcoholic content. Today, most wines are labeled with the name of the grape variety and the location of where the grapes were grown. Such labeling was made possible by the TTB, which issued new labeling regulations in response to consumer demand for more information.

Under the 1978 regulations, wines can carry a varietal designation if at least 75% of the wine was produced from the named grape variety. Wines may carry a geo-political designation, such as “Napa County,” if 75% of the grapes came from the named geo-political region. The 1978 regulations also allowed the creation of “American Vineyard Appellations” (AVAs). AVAs can be large, covering several states, or very small, nestled within a county. “Napa Valley” is probably the best known AVA (Lapsley, 1996). For a wine to bear an AVA on its label, 85% of the grapes must come from the named AVA.

Appellation has become an important factor in price and profitability for wine grapes, with the location of production being more important economically than the variety. Using Cabernet Sauvignon as an example, the average price for Cabernet from Fresno was under \$500 per ton, while the average price of the same variety grown in Napa was over \$5,000 a ton—an order-of-magnitude difference. Such factors should be considered in greater depth if the proposed regulations are eventually extended to include rules governing location-of-origin labeling.

11.6 Conclusions

The commercial production of alcohol was banned from 1919 to 1934, and it has taken decades since Repeal to determine how alcohol should be assimilated into American society and what levels of control are necessary. Indeed, the discussion of the place of alcohol is still debated and the types and levels of control and taxation vary from state to state, and within state. The regulation of medicinal cannabis is still very much in its infancy, but lessons may be learned by examining how alcohol production, distribution, and sales have evolved in California and other states.

12. Health, safety, community, and environmental benefits

12.1 Potential medicinal benefits of medicinal cannabis

Clinical trials on the benefits of medicinal cannabis find mixed results (Grant et al. 2012; Crippa et al. 2009; Wang et al. 2008). Medicinal cannabis may be an option for treating certain conditions, such as pain or nausea. Part of the reason cannabis works to relieve pain and quell nausea is that, in some people, it is reported to improve mood and/or act as a sedative. Grant et al. (2012) observes that medicinal cannabis may be effective in the treatment of psychiatric disorders or neuropathic pain.

Some findings in the medicinal literature suggest that using cannabis carries psychiatric risks including addiction, anxiety, and psychosis, while other findings suggest that cannabis is an effective treatment for those same conditions. In general, the literature is sparse, especially in top-tier scientific journals. In this SRIA, we do not attempt to evaluate or compare the relative technical merits of conflicting medicinal opinions in an area of neuropsychiatric research that is still in its early stages of development.

12.2 Product safety for medicinal users

Product safety may be one of the most important benefits of legalizing and regulating medicinal cannabis. Pesticide use in agriculture is common, but pesticides and pesticide residues are regulated. Allowable pesticides and residue levels on food crops are

restricted by the U.S. Environmental Protection Agency, and the monitoring of the levels of residues are carried out by the Federal Drug Agency and U.S. Department of Agriculture. However, pesticide use in medicinal cannabis cultivation is not regulated. There are no approved pesticides or application limits established for use on cannabis crops.

Cannabis joints and other common smoking devices often do not include filtration mechanisms, which may be likely to increase the intake of pesticide residues compared with tobacco smoking. Sullivan et al. (2013) investigated the presence of chemical residues on cannabis and the transmission of those residues into the user, and evaluated the presence and extent of 10 different chemical residues using three different smoking devices. Sullivan et al. observed differences between the smoking devices, but they found that the portion of pesticide recovery was generally high enough to be a serious concern (over 50% of residues except in a water pipe with filters).

Given that medicinal cannabis is intended for consumption by medicinal patients, the intake of toxic substances may cause further health complications for medicinal users. Sullivan et al. (2013) also suggests that chemical residues found in cannabis may be the result of obtaining the cannabis products from unregulated product supply chains.

Under the legalization and regulation of the medicinal cannabis market, product testing is an important part of the governance system. A well-executed regulatory approach will help reduce the public health and safety risks that may arise from pesticide exposure or other forms of contamination.

12.3 Environmental effects

The potential environmental impacts of regulated cannabis can be discussed relative to the possible environmental impacts of unregulated cannabis.

It has been reported that unregulated cannabis has been cultivated in national parks and forests and associated with illegal deforestation (Caulkins 2010; National Drug Intelligence Center 2009). Unfortunately, there are no hard data on the extent of cannabis cultivation on public land. However, it is logical to expect that the current level of encroachment and resulting environmental damage on public lands could be greatly diminished or eliminated if regulation shifted cultivation to privately owned land. Private ownership of land used for cannabis cultivation acts as an incentive to preserve the land quality and maintain the long-term productivity.

Illegal outdoor cannabis cultivation sites may have harmful impacts on the environment. Illegal cannabis cultivation is associated with illegally diverted water, soil contamination, the presence of hazardous wastes, and the use of banned fertilizers and pesticides (Drug Enforcement Administration 2016; Wilkey 2013). The Drug Enforcement Administration (DEA) reports that rodenticide and insecticide toxicants that are detrimental to wildlife are frequently discovered on unregulated cannabis cultivation sites (DEA 2016). The DEA also reports that over 110,000 acres of land in California have been destroyed since 2006 due to fires associated with unregulated cannabis cultivation, costing taxpayers more than \$55 million.

A significant share of cannabis is cultivated indoors. Indoor cultivation is a carbon-intensive endeavor that consumes huge amounts of energy. Mills (2012) finds that cannabis energy use costs about \$6 billion annually and that indoor cannabis production may account for 1% of the entire country's electricity consumption.

Specific energy uses by indoor cultivation operations include high-intensity lighting, dehumidification to remove water vapor, space heating during non-illuminated periods and drying, preheating of irrigation water and ventilation and air-conditioning to remove waste heat (Mills 2012). Substantial energy inefficiencies arise from air cleaning, noise and odor suppression, and use of inefficient electric generators to avoid conspicuous utility bills. One-third of the energy used by indoor growing operations comes from the lighting;

the rest is devoted to ventilation, heating, dehumidification, and air conditioning (Mills 2012; Bullis 2014).

One reason for the current proliferation of indoor cultivation operations is also that they are the more inconspicuous to authorities. Insofar as state regulation enables and compels cultivators to be openly licensed and monitored by state authorities, the risk-reduction incentives to run warehouse growing operations in situations where they are less efficient are eliminated. Thus, regulation may further push investment in legal cannabis production toward more efficient greenhouse operations that use less energy inputs.

This effect will likely be amplified by the increased availability of investors willing to participate in capital-intensive projects like greenhouse construction. Of course, these cultivation impacts are not the direct focus of the analysis in this appendix.

The nexus of movement toward greenhouse cultivation resulting from the proposed regulations is likely to reduce the negative environmental impact of indoor artificial-light cultivation, as well as reducing carbon emissions and more efficiently allocating and thus conserving public resources such as water and farmland.

13. A primer on IMPLAN methodology

13.1 Introduction

The most common and widely accepted methodology for measuring the economic impacts of specific industries is input-output (I-O) analysis, a subset of a family of methods called social accounting models (Shaffer, et al. 2004; Hewings 1986).

Input-output models are helpful to describe an array of economic transactions between various sectors in a defined economy for a given period, typically one year. These models not only provide researchers with estimates of the scalar multipliers but also support a detailed decomposition of the multipliers.

Like any economic model, the one presented in this SRIA is an abstraction of the real world and depends on assumptions that may be imperfect. Studies that document the economic impact of industries or changes in industries seldom discuss these limitations.

Input-output models are used descriptively and analytically to demonstrate the relative importance of a business, industry, or sector, such as the California almond industry (Sumner et al. 2014, Sumner et. al. 2015), and to estimate the economic responses from alternative actions such as the establishment of a new regulatory structure for the California medicinal cannabis industry.

Input-output analysis is attractive in part because it provides fairly straightforward results. Another appeal of I-O analysis is that it uses multiplier effect to calculate the total impact, which is broader than simple direct effects.

13.2 Using IMPLAN to project economy-wide impacts from wholesale and retail industries

In I-O analysis, one common source of misleading impact estimation is the inclusion of the value of goods sold in sectors that serve as intermediaries between the producer and the consumer. Wholesale and retail are examples of sectors that work with margins, which are calculated as sales receipts less the cost of the goods sold, plus sales taxes and excise taxes that are collected by the trade establishment (Day et al., 2012).

To account for economic impacts of wholesale and retail properly, it is necessary to conduct the analysis considering only the margins of these sectors, and to model the value of goods sold as part of their production processes. In correctly applied margins, the direct effect is distributed among all contributing sectors to reflect each sector's proportion of the total sales value. This not only correctly distributes the sales value, but also ensures the appropriate total effects on the region. Under this approach, separate impacts from production, transportation, wholesale, and retail can be added up, avoiding double counting of the value of the vertical chain between farm and end consumer.

Running impact analysis using margins is often applied for various settings including vineyards and wine (Michaud et al. 2016), retail sales (Sullivan et al. 2012), and food (Jablonski et al. 2016). Crompton et al. (2015) discusses double counting and other issues involved in conducting impact analyses.

13.3 Input-output methodology

An Input-output model offers a “snapshot” of the economy, detailing the sales and purchases of goods and services between all sectors of the economy for a given period of time within a conceptual framework derived from economic theory. The activities of all economic agents (industry, government, households) are divided into a specified number of production sectors.

The transactions between the sectors are measured in terms of dollars and segmented into two broad categories: non-basic, which includes transactions between local industries, households and other institutions; and basic, which includes transactions

between industries, households, and other institutions outside the economy being modeled (i.e., imports and exports). One can think of an I-O model as a large "spreadsheet" of the economy where columns represent buying agents in the economy.

These agents include industries within the economy buying inputs into their production processes; households and governments purchasing goods and services; and industries, households, and governments that are located outside the region of analysis. The last group represents imports into the economy.

Economic agents can import goods and services into the regional economy for two reasons. First, the good or service might not be available and must be imported. Second, local firms might produce or supply the imported good or service, but the local prices or specifications might not meet the needs of the purchasing economic agents. The columns represent economic demand. The rows of the "spreadsheet" represent selling agents in the economy or supply. These agents include industries selling goods and services to other industries; and households, governments, and consumers outside the region of analysis. The latter group represents exports out of the economy. Households that sell labor to firms are also included as sellers in the economy.

A key assumption in the construction and application of input-output modeling is that supply equals demand. In the framework of the "spreadsheet of the economy" outlined above, the row total (supply or industry revenue) for any particular industry equals the column total (demand or expenditures): the "spreadsheet of the economy" must be balanced. This framework enables analysis of how changes in one part of the economy affect the whole of the economy.

In this analysis, for example, the introduction of regulations to the medicinal cannabis industry might increase demand for cannabis products. To meet this new, higher level of demand, cannabis supply must increase. Increasing production requires the purchase of additional flowers, the purchase of additional equipment from manufacturing, purchase of additional professional services, and/or more use of labor.

These other sectors must also increase production, and their corresponding inputs, to meet the new level of demand created by an increase in manufactured cannabis products. The new labor hired has higher levels of income, part of which is in turn spent in the regional economy. The increased demand for cannabis products creates a ripple or “multiplier” effect that can thus be measured across the whole economy and applied to the impact assessment.

13.4 Input-output multipliers

In the input-output model “spreadsheet of the economy,” any change ripples across the entire economy. By manipulating the empirical I-O model, it is possible to compute a unique multiplier for each sector in the economy.

These multipliers provide insight in the analysis of policy regulations of the California medicinal cannabis industry and are used to estimate the economic impact of alternative regulatory policies to the economy. In addition, the multipliers can identify the degree of structural interdependence between the medicinal cannabis industry and the rest of the economy. The sector output multiplier described here is among the simplest input-output multipliers available. By employing a series of fixed ratios from the input-output model, researchers can create a set of multipliers ranging from output to employment multipliers, as shown in Table 13.1.

The income multiplier represents a change in total income (employee compensation plus proprietary income) for every dollar change in output in any given sector. The value-added multiplier measures change in total income and profit minus business taxes for every dollar in additional output by the sector. The employment multiplier represents the total change in employment resulting from the change in output in any given sector. Thus, changes in economic activity can be estimated in four ways.

Table 13.1. Understanding multipliers

| Type | Definition |
|-------------------------------|---|
| Output multiplier | The output multiplier for an industry measures the sum of direct and indirect requirements from all sectors needed to deliver an additional dollar-unit of output of that industry to final demand. |
| Income multiplier | The income multiplier measures the total change in income throughout the economy from a dollar-unit change in final demand for any given sector. |
| Value added multiplier | The value added multiplier measures the total change in labor income and profit minus business taxes throughout the economy from a dollar-unit change in final demand for any given sector. |
| Employment multiplier | The employment multiplier measures the total change in employment due to a one-unit change in the employed labor force of a particular sector. |

13.5 Initial, indirect, and induced effects

Construction of the multipliers allows us to decompose the multiplier effect into three parts: (1) the direct effects; (2) the indirect effects; and (3) the induced effects. Direct effects represent the initial change in the industry in question (e.g., in the industry itself). Indirect effects are changes in inter-industry transactions when supplying industries respond to increased demands from the directly affected industries (e.g., impacts from non-wage expenditures). Induced effects reflect changes in local spending that result from income changes in the directly and indirectly affected industry sectors (e.g., impacts from wage expenditures).

The initial effect is associated with the scenario that creates the impact on the economy. In the medicinal cannabis example, this is the increase in medicinal cannabis sales. To produce the additional output, the firm or industry must purchase additional inputs.

The inputs take two forms: purchases from other businesses, and labor. Purchases from other businesses creates the indirect effect. Labor creates the induced effect. For a particular producing industry, multipliers estimate the three components of total change within the region of interest.

Comparing and contrasting the indirect and induced effects can offer important insights. Under the input-output framework assumptions, industries that are more labor-intensive will tend to have larger induced effects and smaller indirect effects. Industries that tend to pay higher wages and salaries will also tend to have larger induced effects. Decomposing the multiplier into its induced and indirect effects can provide a better understanding of the industry under examination and its relationship to the larger economy.

Although input-output analysis is a useful economic tool for examining the impacts on an economy from changes in a particular industry, it does have some limitations in its assumptions. For example, I-O analysis assumes that production technology and returns to scale are constant.

In other words, production technology does not vary across industries and does not evolve. These assumptions lead to the model being static. There is no allowance for adjustments due to advancements in technology or industry practices.

13.6 Modeling system

The input-output modeling system used in this study is IMPLAN (Impact M for Planning), originally developed by the USDA Forest Service. A product of the Rural Development Act of 1972, IMPLAN is a system of county-level secondary data input-output models designed to meet the mandated need for accurate, timely economic impact projections of alternative uses of U.S. public forest resources. IMPLAN is now operated by the Minnesota IMPLAN Group (MIG).

At the heart of the IMPLAN model is a national input-output dollar flow table called the Social Accounting Matrix (SAM). Unlike other static input-output models, which only measure the purchasing relationships between industry and household sectors, a SAM is an organized matrix representation of all transactions and transfers between different production activities, factors of production, and institutions (households, corporate sector, and government) within the economy and with respect to the rest of the world.

A SAM is thus a comprehensive accounting framework within which the full circular flow of income—from production to factor incomes to household income to household consumption and back to production—is captured. All the transactions in the economy are presented in the form of a matrix in a SAM. Each row of the SAM gives receipts of an account, and the column gives the expenditure. Using the SAM allows IMPLAN to model transfer payments such as unemployment insurance.

Another advantage of the IMPLAN system is its design allows users the ability to alter the underlying structure of the data, the model, or means of assessing impact.

The combination of the detailed database, flexibility in application, and open-access philosophy has made IMPLAN one of the most widely used and accepted economic impact modeling systems in the United States.

To assess the economic impact of medicinal cannabis segments, we employed IMPLAN 2014 at the county level using the most recently available IMPLAN database.

14. Issues that may lead to especially large ranges of uncertainty surrounding our simulated impacts of regulations

1. Equilibrium assumptions. Our estimates in this SRIA assume that the market has moved to a new equilibrium that incorporates the supply and demand shifts caused by state and local regulations, taxes, tourism, and other supply and demand effects we expect to occur upon.

All methods of economic modeling have their advantages and drawbacks. One of the drawbacks of equilibrium displacement modeling (EDM), our chosen method, is that it compares two static equilibria and does not consider the intermediate time period during which the market is adjusting to new conditions. Among the corresponding advantages are that EDM generates numerical estimates that meet the statutory requirements for a SRIA and are compatible with the IMPLAN method of analyzing economic impacts and ripple effects.

2. Time horizon. The mandate of a SRIA is to estimate the economic impact in the 12 months after the regulations go into effect. The equilibrium estimates developed and reported in this SRIA are based on a model that assesses the impacts of the regulatory changes on consumer and producer behavior and therefore prices and quantities.

However, the amount of time it will take the market to reach the new equilibrium is highly uncertain. We expect that even some time, perhaps several months after the proposed regulations are fully implemented the market will display the volatility of an immature market in the midst of structural change. All of our estimates should be interpreted with this in mind.

Some of the most immediate and unpredictable effects of the regulations are short-term disequilibria as the industry matures and companies respond to rapidly changing market incentives. Sources of uncertainty with respect to time include the speed at which businesses reconfigure and adapt to the new regulations; the speed at which full-scale

local and state-level regulatory enforcement and tax collection systems to be put into place; the speed at which the Bureau and other state agencies are able to process license applications, perform background checks, and issue licenses; and the effects of the temporary emergency regulations during the first half of 2018, which include some but not all of the proposed regulations.

Beyond the uncertainty of the time to reach equilibrium, it is difficult to predict the behavior of businesses during the transition phase, especially with respect to compliance and risk choices during the initial period when enforcement is not yet at full scale. For our impact calculations we assume that a new market equilibrium has been reached after the full implementation of the proposed regulations by all relevant California agencies, including full-scale enforcement, track-and-trace, and tax collection systems.

3. Local taxation. Neither the proposed Bureau regulations nor MAUCRSA set any legal upper limit on the ability of local counties or municipalities to impose their own taxes. The proposed Bureau regulations require that licensees be compliant with their local tax and regulatory systems. This introduces two kinds of uncertainty into our SRIA analysis.

First, throughout 2017 and into 2018, local tax laws were being decided on an ongoing basis all over the state. Some municipalities already had concrete systems and enforcement mechanisms in place as of January 1, 2018. Some had discussed and/or proposed tax structures but had not yet voted on them. Some were in the process of changing rules that had been established earlier (for instance, amending medicinal cannabis regulations to include the adult-use industry). Others are still silent on local taxation and regulation of the cannabis industry.

It is important to note that the levels of taxation set by many of the jurisdictions that have already imposed cannabis tax schedules are impactful. The modal system, at this writing, imposes a flat revenue tax of 10%. Such tax rates are sufficient to have a notable effects on our simulation results for prices and quantities, and they raise the effective tax rate on legal retail cannabis relative to the price of illegal cannabis.

Of course, in our estimates of the impacts of the proposed Bureau regulations, we separate the costs of state-level taxation from those of local taxation; however, we do not calculate the impacts generated by each taxation source individually. It is important to consider the overall economic impacts in light of the fact that our Taxation Baseline incorporates a significant contribution to costs from local taxation and regulation. We also recognize that the substantial variation in local taxes and local regulations will affect the geographic distribution of economic activity associated with legal and regulated cannabis.

Another area of uncertainty with respect to local taxation is the movement of businesses and consumers to jurisdictions outside their own (either for buying cannabis, selling cannabis, or ordering cannabis for delivery) if neighboring areas have tax or regulatory (and therefore cost) advantages. These effects may, to some extent, mitigate the local tax burden and impact state-wide averages. In this SRIA, we do take a weighted approach to the aggregation of state tax averages from local tax levels. To quantify precisely such industrial organization effects would be outside the scope of this SRIA.

4. Cultivation taxation and effects on outdoor-grown cannabis. Taxes imposed on cultivators are outside the scope of our proposed Bureau regulations analyzed in this SRIA. However, these taxes are sources of uncertainty that affect the estimates within our scope. Comparisons between California and other states are particularly weak when it comes to the effect of cultivation taxes. First, no state has implemented a state-level cultivation tax similar to California's other than Alaska, a state whose small population and high (\$800 per pound) cultivation tax make comparisons to California less relevant.

To complicate things further, in California, many local tax jurisdictions have chosen to tax cultivators per square foot under canopy. Because outdoor yields per unit of area are lower, this results in an effective tax rate per pound on outdoor cannabis that may average much higher than the effective tax rate on indoor cannabis.

A change in the concentration of outdoor-grown cannabis on the marketplace may have effects whose size is difficult to predict. Throughout 2017, the wholesale price of outdoor

cannabis fluctuated around approximately \$1,100 per pound, whereas greenhouse and indoor cannabis were in the ranges of \$1,500 and \$1,800 per pound, respectively.

Aggregate average wholesale prices are driven not only by the price of each grow type, but also by the percentage of product on the market coming from each of the three grow types. Therefore, the changes in the share from each source raises uncertainty about the prices entering the legal cannabis market from the cultivators.

5. Industrial organization and geographical location. Projecting impacts of regulatory change on size distribution of companies in a market and how they relate to one another along the supply chain is always especially difficult. Such difficulty is magnified here because we have no accurate historical data.

Both consolidation among firms at the same stage in the supply chain (e.g. consolidation among retailers) and vertical consolidation (consolidation between retailers and distributors) may occur in the cannabis market. The average size of businesses may increase due to consolidation undertaken by businesses in order to capture increased efficiency with respect to compliance with the new regulations or for many other reason as the new legal and regulated market emerges.

For example, in the case of testing, we build our estimates in part on the expectation that there will be approximately 20 testing firms for legal cannabis. There is uncertainty in this and related estimates (e.g. average firm size, number of employees per firm, and so on), as currently operating testing businesses testing regulations in Colorado, Washington, and Oregon are different enough from California's that between-states comparisons are of limited value.

Industrial organization effects, like the other effects discussed in this section, are not easily incorporated into our aggregate estimates of the impacts of the proposed Bureau regulations. Some such effects may not affect prices, quantities, or the total value of the

industry, while still affecting the numbers of businesses and the geographical distribution of businesses.

6. Tourism. The outward demand shift that we incorporate as an impacts of legalization and the proposed Bureau regulations are in part associated with an incipient cannabis tourism industry. Such an effect is particularly difficult to estimate. Some researchers have reported a dramatic impact of cannabis tourism in Colorado—a state that, like California, already has a booming tourist industry—while others have reported only modest gains.

Another area of uncertainty with respect to tourist demand lies in to what extent the “coffee shop” business model (on-premise consumption) is allowed by local regulations and is successful in California. Yet another is the known negative self-reporting bias in cannabis consumption surveys, a bias that may be stronger amongst tourists who may have an incentive to under report that they have used drugs that are illegal in their home states.

7. Demand among residents. Self-reported use rates, which are used in some of the methodologies we employ to predict market size in this SRIA, are also associated with other uncertainties beyond predicting tourist demand. Self-reported use rates have been known to jump dramatically when states legalize adult-use cannabis (29% in Colorado, for instance), and it is not known to what extent this effect can be attributed to actual increased use vs. a diminishing negative self-reporting bias as cannabis becomes less of a taboo in the state.

Our estimates for tourist demand, and overall demand, should be taken with all of the above uncertainties and caveats in mind.

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